PROPOSED PROSPECTIVE REIMBURSEMENT RATES FOR THE END-STAGE RENAL DISEASE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

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PROPOSED PROSPECTIVE REIMBURSEMENT RATES FOR THE END-STAGE RENAL DISEASE PROGRAM

MONDAY, MARCH 15, 1982

U.S. SENATE,
SUBCOMMITTEE ON HEALTH,
SENATE FINANCE COMMITTEE,
Washington, D.C.

The committee met, pursuant to notice, at 9:05 a.m., in room 2221, Dirksen Senate Office Building, Hon. David Durenberger (chairman) presiding.

Present: Senators Dole, Durenberger, and Baucus.

[The press release announcing the hearing and background material relating to the hearing and the prepared statement of Senator Durenberger follow:]

[Press release, Feb. 25, 1982]

SENATE FINANCE SUBCOMMITTEE ON HEALTH SETS HEARING ON THE PROPOSED PROSPECTIVE REIMBURSEMENT RATES FOR THE END-STAGE RENAL DISEASE PROGRAM

The Honorable Dave Durenberger (R., Minnesota), Chairman of the Subcommittee on Health of the Committee on Finance, announced today that the Subcommittee will hold a hearing on Monday, March 15 to review the proposed prospective reimbursement rates for the end stage renal disease (ESRD) program. The hearing will begin at 9:30 a.m. in Room 2221 of the Dirksen Senate Office Building. This hearing is the second part of the hearing which began on September 28, 1981. Part I focused on program operations and management including the role of the networks. Part II will consider the equity and effectiveness of the prospective reimbursement rate structure proposed by the Secretary of Health and Human Services on February 12, 1982.

Senator Durenberger noted that "the long delay in implementing an incentive reimbursement rate as first required in 1978 is a result of the controversy over the level at which ESRD treatments should be reimbursed. The Subcommittee is concerned that in setting the newly proposed rates the Department may not have adequately considered some key issues that underlie the controversy. It is also concerned that the proposed regulations may not be responsive to the intent of the Congress when it passed the Omnibus Budget Reconciliation Act of 1981".

Senator Durenberger stated that "renal patients will not be allowed to suffer or perish because of the proposed rates . . . facilities will not be allowed to exclude or reject older or seriously ill patients . . . and physicians will not be allowed to inappropriately place patients on home dialysis in order to take advantage of the monetary incentives provided in the new rates if those patients are not medically, socially, and psychologically suited to home care".

Senator Durenberger went on to say that the Subcommittee would like to hear from both patient and provider groups as well as the administration, the HHS Inspector General and the U.S. General Accounting Office. Specifically, the Subcommittee expects to hear testimony at the March 15 hearing which addresses: The adequacy of the data on which the administration based the new rates; the adequacy of the rate setting methodology; the ability of providers to adapt to the new rates, and the potential effect the new rates will have on patients, physicians and facilities.

APPENDIX C TO COMMITTEE PRINT 97-12

Committee Print 97-12, "Proposed Prospective Reimbursement Rates for the End-Stage Renal Disease (ESRD) Program Under Medicare", prepared by the staff for the use of the Committee on Finance, dated March 1982, contained a staff analysis of patient case mix. The following presents the methodology employed, additional details of the analysis, and revised analysis results for admission, patient day, and length of stay parameters. This information was not available in time to be included in the committee print as Appendix C.

METHODOLOGY

The "patient mix" analysis reported in committee print 97-12 was based on the HCFA Master file data, processed at the Senate Computer Center. The decision to focus on differences within large metropolitan areas necessitated identifying and grouping providers located in Standard Metropolitan Statistical Areas and New England Metropolitan Statistical Areas. Ultimately 383 non-federal, non-pediatric outpatient hemodialysis providers, located in 19 SMSA's with 10 or more providers were selected. For each selected provider, all 1980 quarterly dialysis records (HCFA type 'g' records) were accumulated, yielding a file with total dialysis sessions for each patient/provider combination. The file was then transformed to a patient analysis file by aggregating dialysis sessions for each patient by type of provider. Finally, patient history data (HCFA type "A" records) and accumulated 1980 hospital admissions and number of inpatient days (HCFA type 'E' records) were added to each patient record. The general composition of the patient analysis file is presented in the following table.

GENERAL COMPOSITION—PATIENT ANALYSIS FILE

Standard metropolitan statistical area	Providers	Patients
Anaheim-Santa Ana-Garden Grove, Calif.	11	365
Hospitals	8	242
Clinics	3	123
Atlanta, Ga.	12	764
Hospitals	4	141
Clinics	8	623
Baltimore, Md.	12	463
Hospitals	7	178
Clinics	5	285
Boston, Mass.	11	806
Hospitals	9	325
Clinics	2	481
Chicago, Ill.	46	2,078
Hospitals	23	745
Clinics	23	1,333
Dallas-Fort Worth, Tex.	14	925
Hospitals	6	32
Clinics	8	893
Denver-Boulder, Colo.	11	553
Hospitals	6	224
Clinics	5	329
Detroit, Mich.	16	1,013
Hospitals	13	706
Clinics	3	307

GENERAL COMPOSITION—PATIENT ANALYSIS FILE—Continued

Standard metropolitan statistical area	Providers	Patients
Houston, Tex.	11	642
Hospitals	5	251
Clinics	6	391
Los Angeles-Long Beach, Calif.	49	1,141
Hospitals	20	291
Clinics	29	850
Miami, Fla.	19	1,026
Hospitals	9	247
Clinics	10	779
Nassau-Suffolk, N.Y.	13	611
Hospitals	11	465
Clinics	2	146
New Orleans, La.	12	373
Hospitals	7	89
Clinics	5	284
New York, N.Y.-N.J.	48	3,160
Hospitals	37	1,875
Clinics	11	1,285
Newark, N.J.	13	922
Hospitals	9	506
Clinics	4	416
Philadelphia, Pa.-N.J.	30	1,618
Hospitals	16	641
Clinics	14	977
San Francisco-Oakland, Calif.	21	1,240
Hospitals	12	662
Clinics	9	578
St. Louis, Mo.-Ill.	10	483
Hospitals	7	195
Clinics	3	288
Washington, D.C.-Md.-Va.	24	1,022
Hospitals	10	100
Clinics	14	922
Total	385	19,205
Hospitals	219	7,915
Clinics	166	11,290

STATISTICAL SIGNIFICANCE

A number of tests of statistical significance were performed on the comparisons of patient condition vs. type of treatment facility. Tests of statistical significance for the major comparisons made in the table on page 23 and table 2 on page 26 of the committee print are presented below. While the differences found in each of the

comparisons are statistically significant, this does not mean those differences have any substantive clinical significance.

TEST OF STATISTICAL SIGNIFICANCE

ESRD PATIENT HOSPITAL UTILIZATION IN 1980 IN MAJOR METROPOLITAN AREAS WITH 10 OR MORE ESRD FACILITIES

	Number of—		Average length of stay
	Admissions	Inpatient days	
Patient definition based on primary diagnosis: Mean values:			
Sicker	1.62	17.17	6.81
Normal	1.28	13.08	5.46
T-Statistic (d.f. + 4621)	6.71	5.55	4.98
Probability T	9.81×10^{-12}	1.46×10^{-8}	3.22×10^{-7}

Source: Committee Print 97–12, p. 23.

PERCENT OF PATIENTS TREATED IN 1980 BY FACILITY TYPE AND PRIMARY DIAGNOSIS IN MAJOR METROPOLITAN AREAS WITH 10 OR MORE ESRD FACILITIES

Frequency column percent	Facilities with exception		Facilities without exception		All facilities	
	Number	Percent	Number	Percent	Number	Percent
Sicker patients	1,170	49.62	2,404	52.85	3,574	51.75
Normal patients	1,188	50.38	2,145	47.15	3,333	48.26
All patients	2,358	34.14	4,549	65.86	6,907	100.00

The Chi Square Tests concludes with slightly less than 99 percent confidence that the proportion of sicker patients differs among facilities with and without exceptions ($X^2=6.483$, $P=0.0109$).

Source: Committee Print 97–12, p. 26.

PERCENT OF PATIENTS TREATED IN 1980 BY FACILITY TYPE AND PRIMARY DIAGNOSIS IN MAJOR METROPOLITAN AREAS WITH 10 OR MORE ESRD FACILITIES

Frequency column percent	Hospital-based facilities		Independent facilities		All facilities	
	Number	Percent	Number	Percent	Number	Percent
Sicker patients	1,588	49.35	1,986	53.84	3,574	51.74
Normal patients	1,630	50.65	1,703	46.16	3,333	48.26
All patients	3,218	46.59	3,689	53.41	6,907	100.00

The Chi Square Test concludes with over 99.9 percent confidence that the ratio of sicker to normal patients differs among hospitals and clinics ($X^2=13.866$, $P=0.0002$).

Source: Committee Print 97–12, p 26.

REVISED ANALYSIS RESULTS

ESRD PATIENTS HOSPITAL UTILIZATION IN 1980 FOR PATIENTS WITH UNREPORTED PRIMARY DIAGNOSIS IN MAJOR METROPOLITAN AREAS WITH 10 OR MORE ESRD FACILITIES

	Hospital-based dialysis patients		Independent dialysis patients	
	With exception	No exception	With exception	No exception
Admissions:				
Mean	1.63	1.43	1.08	1.37
Standard error	.05	.05	.10	.03

ESRD PATIENTS HOSPITAL UTILIZATION IN 1980 FOR PATIENTS WITH UNREPORTED PRIMARY DIAGNOSIS IN MAJOR METROPOLITAN AREAS WITH 10 OR MORE ESRD FACILITIES—Continued

	Hospital-based dialysis patients		Independent dialysis patients	
	With exception	No exception	With exception	No exception
Patient days:				
Mean	16.92	15.49	10.78	13.53
Standard error	.77	.69	1.31	.38
Length of stay:				
Mean	5.57	6.62	4.49	5.85
Standard error	.34	.33	.46	.16

Note: All patients treated in both types of facilities and all patients not on dialysis for the full year were eliminated from the analysis.

Source: Committee Print 97-12, p. 24

OPENING STATEMENT OF SENATOR DOLE

The ESRD program has been a medical success. It has provided the means by which the lives of a growing number of patients are sustained. Gone are the committees that met to determine which patients would be allowed access to the few dialysis machines available.

Public Law 92-603, enacted in October 1972, changed all that by extending medicare coverage for dialysis and kidney transplants to all Americans with end stage renal disease.

The program, however, has not been an administrative success. Program costs have grown significantly, home dialysis—once a vigorous part of the program—has languished, barriers to lower cost treatment modalities still exist, networks have had only limited success, program data is inadequate to estimate patient mortality and morbidity and to determine relative costs, patient access to facilities and physicians of choice is restricted, and patient grievance mechanisms are fragmented.

These are but some of the problems heard at the first hearing held in September 1981. I would hope that the department acts to correct these and other program problems.

Today, we want to consider the regulatory changes being proposed by the Department to establish a prospective reimbursement system. The proposed changes will have significant economic effects, particularly on hospital-based dialysis facilities. But more importantly, the proposed changes will affect patients, and they are my deepest concern.

I am very distressed to hear some of the things patients have been told about the intent of Congress and these proposed regulations; that we intend to indiscriminately shift patients into home dialysis, have patients "suffer or perish", make in-facility dialysis financially unfeasible, and return to the days of home treatment for a privileged few and judgment by death committees for the rest.

Nothing could be further from the truth. We intend to see that quality medical care is available to all patients, and we expect physicians to determine what is best for their patients based on their medical needs, not on some profit maximization basis. I look forward to hearing from our witnesses today. Their testimony, I hope, will provide some straightforward answers to questions about how the new rates will be set, whether providers can adapt to them, and what potential effect the proposed reimbursement system will have on patients, physicians, and facilities, without the rhetoric and misinformation that has been heard recently about what the Congress or Secretary Schweiker is attempting to accomplish.

OPENING STATEMENT OF SENATOR DURENBERGER

The ESRD program has provided access to the medical technology needed to treat all Americans with permanent kidney failure. I am firmly convinced, indeed committed, to the notion that adequate care will be available for all ESRD patients now and in the future. Contrary to what some people have said, renal care will not be rationed. We must, however, examine alternative ways to provide renal care in light of the growing cost of the program and current budget climate. The prospective reimbursement system proposed by the Secretary is such an alternative.

An incentive reimbursement rate was first required in 1978. Since then, HCFA had considered first, separate rates for each type of facility—hospital-based and independent—and later, setting one rate for all facilities.

The finance committee, however, expressed concern about the single rate proposal, noting that it could have a negative impact on the continued participation of hospital-based facilities and on the objective of encouraging lower cost home dialysis for those patients medically, socially, and psychologically suited to home care. Thereafter, Congress amended the law to require prospectively determined rates on the basis of separately calculated formulas for hospital-based and independent facilities.

We are now concerned that the Secretary may not have addressed some key issues that underlie the controversy over the level at which ESRD treatments should be reimbursed. And we are also concerned that the proposed regulations may not be responsive to the intent of Congress when it passed the Omnibus Reconciliation Act of 1981.

Let me make it clear, however, that we do not intend to allow renal patients to suffer or perish because of these or any other proposed regulations. Nor do we intend to allow facilities to exclude or reject older or seriously ill patients. Nor will physicians be allowed to inappropriately place patients on home dialysis in order to take advantage of the monetary incentives provided in the new rates.

I look forward to hearing from our witnesses today, particularly as to how the proposed regulations will affect all concerned.

Senator DOLE. We are prepared to begin a subcommittee hearing this morning. I am filling in for Senator Durenberger who should be here about 10 o'clock. Senator Baucus is on his way to the committee room. And I might suggest, since there are 14 witnesses, we will try to expedite the hearing. We would hope that any formal statements can be summarized so we will have some time for questions, because if we did nothing else than have you read your statement, it would take us beyond the time that I think Senator Durenberger needs to complete the hearing.

I would just say in a preliminary way that the ESRD program has been a medical success and an administrative disaster. And it is my hope that we can have some objective testimony, not on how much profit ought to be made but how the program works and how we can reduce the cost of the program. We have a wide range of witnesses who are certainly familiar with the program. There has been a lot of scare talk, or at least leaflets that I have read about patients who are going to lose their benefits and things of that kind which we believe are irresponsible, at least I do.

The program has not been an administrative success.

Program costs have grown significantly; home dialysis, once a vigorous part of the program, has languished; barriers to various lower cost treatment modalities still exist; networks have had only limited success; program data is inadequate to estimate patient mortality and morbidity and to determine relative costs; patient access to facilities and physicians of choice is restricted, and patient grievance mechanisms are fragmented.

These are some of the problems first heard in the hearing held last September 1981. We hope by now that the Department has some plan to correct these and other program problems.

Today we want to consider the regulatory changes being proposed by the Department to establish a prospective reimbursement system. The changes will have a significant economic effect, particularly on hospital-based dialysis facilities. But, more importantly, the proposed changes will affect patients and they are my deepest concern. I am distressed to hear some of the things patients have been told about the intent of Congress and these proposed regulations, that we intend to indiscriminately shift patients into home dialysis, have patients "suffer or perish," make in-facility dialysis financially unfeasible, and return to the days of home treatment for a privileged few, and judgment by death committees for the rest. Nothing could be further from the truth. We intend to see that the quality of medical care is available to all patients, and we expect physicians to determine what is best for their patients based on their medical needs, not on some profit maximization basis. So I look forward to hearing the testimony as a member of this subcommittee and chairman of the committee.

We have had enough rhetoric. We want information. We are not interested in who can make the most money in this program. We are interested in who can best serve the patients in this program.

Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman. When the end-stage renal disease program was enacted in 1972, renal dialysis was a new medical procedure. Only a few thousand patients were being treated and charges for the dialysis treatments varied widely. Nevertheless, the bills had to be paid and medicare selected a national limit of $138 per treatment based on the little bit of information that was available.

Medicare spent the next several years trying to determine whether its payment rate was in line with the cost of treatment, but the facilities resisted the Government's efforts to obtain the necessary cost information. Legislation, which was enacted in 1978, was necessary to require the renal dialysis facilities to report their costs. And now, several billion dollars later, we have partially audited cost reports that show that, for freestanding units, cost per treatment is $108, $30 less than the $138 now being paid. And in the interests of economy, the Department of Health and Human Services is proposing to reduce the $138 payment to $128, thus reducing the average profit from about 30 percent to 17 percent.

While some would contend that a 17-percent profit represents a windfall that medicare could ill afford, some renal dialysis facility owners are telling their patients that they cannot operate at the $128 per treatment and that they will have to close down so that some patients will be deprived of life-sustaining services. Many worried renal patients have been told that one renal dialysis corporation will have to close at least 60 facilities if the new rates go into effect.

These assertions, and the claim that the proposed regulations would compel patients to dialyze at home contrary to their own best interests, are serious charges which cause grave concern to renal patients, for they depend on these facilities for their very survival. These charges deserve close scrutiny.

In the case of hospital-based ESRD facilities, audits show the average cost per treatment to be $135. For these, the Department proposes a payment rate of $132, an average loss of $3 per treatment. HHS argues that the average hospital should be paid less than its actual costs because it is inefficient. The hospitals argue that their higher costs are justified, in part because they treat more costly patients. I look forward to hearing from both the administration and the hospitals about the factual information on which these claims are based. Thank you, Mr. Chairman.

Senator DOLE. Thank you, Senator Baucus.

Our first witness will be Mr. Michael Zimmerman, Associate Director, Human Resources Division, U.S. General Accounting Office.

STATEMENT OF MICHAEL ZIMMERMAN, ASSOCIATE DIRECTOR, HUMAN RESOURCES DIVISION, U.S. GENERAL ACCOUNTING OFFICE, WASHINGTON, D.C.

Mr. ZIMMERMAN. Mr. Chairman, I have a rather lengthy statement and I would like to submit the statement for the record and take time this morning to briefly summarize it.

Senator DOLE. The entire statement will be part of the record, and we consider your testimony to be vital to these hearings. So we want to spend some time. You may summarize it in any way you wish. You might want to introduce those who are with you.

[The prepared statement follows:]

United States General Accounting Office
Washington, D.C. 20548

FOR RELEASE ON DELIVERY
Expected at 9:00 a.m. EST
Monday, March 15, 1982

Statement of Michael Zimmerman
Associate Director, Human Resources Division
Before the
Subcommittee on Health
Senate Committee on Finance
On the Data Used by the Health Care Financing Administration
in Preparing Its Proposal to Establish a Prospective
Reimbursement System for the End Stage Renal Disease Program

Mr. Chairman and Members of the Subcommittee, we are pleased to be here today to discuss our ongoing review of reimbursement issues in Medicare's end stage renal disease (ESRD) program. As requested, our discussion will focus on the data used by the Health Care Financing Administration (HCFA) in preparing its recent proposal to establish a prospective reimbursement system for paying for home and outpatient dialysis treatments under the ESRD program. We will also provide some information on physician compensation in the ESRD program where the related costs are generally reflected in the prospective payment rates and briefly discuss the role of ESRD networks in administering the program. We will be issuing a report on our overall review.

In summary, we believe that the data HCFA used, and the resulting proposed ESRD payment rates, probably overstate what it would cost an efficient and economical provider to deliver needed services. In particular, we question the accuracy of the cost data obtained on independent ESRD facilities because of the incomplete audits on which the data is based.

Specifically:

--The 13 facilities we reviewed reported $15.4 million in costs, including about $6 million in related organization transactions that had not been adequately examined to eliminate inter-company profits and other unallowable costs.

--Physician-owner compensation for administrative services and profit sharing arrangements were included in the audited costs without assessing their reasonableness. These annual payments we were able to identify ranged as high as $360,000 per facility in addition to whatever the the doctors received from Medicare for providing ESRD medical services.

Background

The Social Security Amendments of 1972 (Public Law 92-603) provided Medicare coverage to persons suffering from kidney (renal) failure who are either currently or fully insured under the Social Security Act or are dependents of a person currently or fully insured. The program that resulted from this provision is known as the ESRD program. The program is generally considered effective in protecting beneficiaries from the catastrophic costs associated with caring for a person with renal failure. However, the large and rapidly rising costs of the program--from about $230 million in 1974 to an estimated $1.8 billion in F.Y. 1982--have caused great concern about the future of the program.

In 1978, the Congress passed amendments to the ESRD program (Public Law 95-292) designed to encourage patients to dialyze at home which was believed to be less costly. These included (1) a prospective reimbursement system for home dialysis based on paying facilities a target rate and (2) 100 percent reimbursement to facilities for equipment to be used and maintained for home patients. The original objectives of our work were to evaluate the reasonableness of the target rates that had been established and the effectiveness of the new provisions in encouraging patients to dialyze at home. However, when the Congress provided, in the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) for establishing new methods of paying for ESRD services, we began reanalyzing the data gathered in light of these revisions.

We reviewed the audits conducted by Medicare intermediaries for 13 independent facilities and HCFA's adjustments to these audits to determine the reliability of the resulting data. Our analysis of the audits consisted primarily of a review of the audit reports for the cost reporting years ended in 1978 or 1979 and supporting working papers prepared by the auditors. We also reviewed the adjustments made by HCFA and the supporting documentation for the adjustments. In addition, we talked or met with the intermediary auditors and HCFA officials to obtain additional information on the work performed. Our proposed adjustments were discussed with the intermediary auditors.

Our cost data for home dialysis is based on the costs incurred in 1980 for a sample of 656 beneficiaries dialyzing at home as of December 31, 1980. Our sample was drawn from all the home patients residing in 13 States and while the data is representative of these States it cannot be projected to the Nation. We obtained data from all the Medicare claims processing contractors that we could identify as having paid for services provided to our sample beneficiaries. This involved obtaining data from 27 carriers that pay for Medicare part B services such as physicians' services and dialysis equipment and supplies and 21 intermediaries which pay facility based suppliers such as hospitals and independent renal dialysis facilities.

There are two general types of dialysis treatment modes, hemodialysis and peritoneal dialysis, both of which can be performed at home. For hemodialysis, the most widely used mode, blood is taken from the patient's body and passed through a dialysis machine, which filters out body waste before returning the blood to the patient. Under peritoneal dialysis the blood is filtered within the patient's abdominal cavity without leaving the body. There are three variations of peritoneal dialysis--continuous ambulatory (CAPD), intermittent (IPD), or continuous cycling (CCPD). Of the three variations, CAPD has gained popularity. Our review covered patients using each mode of treatment.

HCFA data shows that overall about 17 percent of ESRD beneficiaries dialyze at home. Of those beneficiaries associated with independent facilities about 10 percent dialyze at home and of those associated with hospitals about 23 percent dialyze at home.

HCFA'S PROPOSED REIMBURSEMENT SYSTEM

On February 12, 1982, HCFA published a proposed rule to change the way Medicare pays for outpatient dialysis and related physician and laboratory services. Under this rule, HCFA proposes to establish a composite rate designed to cover the costs of both home and in facility dialysis treatments. A simplified explanation of the composite rate is that it is made up of HCFA's estimated home dialysis costs times the percentage of all ESRD beneficiaries who dialysis at home plus HCFA's estimate of in facility dialysis costs times the percentage of beneficiaries dialyzing in facilities. Each facility will receive a certain payment rate per treatment, adjusted for geographic differences in the cost of labor. According to the proposal the average payment for independent facilities would be $128 per treatment and $132 per treatment for hospital-based facilities. These amounts will be paid regardless of whether the treatment is furnished in the facility or in the patient's home. The proposal would do away with the home target rates and the 100 percent equipment reimbursement payment methods established pursuant to the 1978 amendments. The methods currently used to reimburse physicians for routine support services would also be changed in a manner which HCFA believes will eliminate some of the economic incentives for physicians to treat dialysis patients in the facilities rather than at home.

INDEPENDENT FACILITY AUDITS WERE POORLY DONE

HCFA has proposed the establishment of a prospective reimbursement system to pay for dialysis services in the patient's home and in facilities. We believe that prospective payment systems should be based on the costs which would be incurred by an efficient and economical provider to deliver needed services. In fact, the Congress has required the States to have Medicaid reimbursement systems for hospitals and nursing homes which meet a similar criteria.

In order to determine the level at which efficient and economical providers can deliver needed services, we believe it is necessary to obtain through audit, data on actual reasonable and allowable costs incurred by a statistically valid sample of providers. To see if HCFA had this data, we reviewed 13 of the 38 audits of independent facility costs which the intermediaries had performed and HCFA used in establishing its proposed rates. We do not believe the audits provide HCFA with the data necessary to adequately establish a prospective reimbursement system because the audits did not result in the elimination from the costs reported by the facilities substantial amounts of unreasonable and unallowable costs.

The total costs reported by the 13 facilities were about $15.4 million. Work done by the fiscal intermediaries and HCFA resulted in reductions of about $2 million to the reported costs. Based on our limited review, we estimated that there should have been additional reductions of about $700,000. The adjustments we made would reduce the average cost per treatment for the 13 facilities reviewed by about $5.50. In addition, we believe there are significant amounts of unallowable or unreasonable costs of related organization transactions which should have been eliminated from the facilities' reported costs. However, due to the limited review work done on related organization transactions by the intermediary auditors, we could not determine from the data reviewed how much these adjustments should have been. A more complete audit could have resulted in additional reductions.

Attachment I summarizes the costs and number of treatments for the 13 facilities as reported by them and the adjustments made by the intermediary auditors, HCFA, and GAO. Most of the reductions we made related to

--incorrect allocations of parent company home office and/or regional office expenses,

--insufficient documentation to support management fees charged by related organizations,

--the cost of dialysis treatments provided for patients of other facilities for which those facilities were responsible,

--nonrecurring and/or undocumented legal expenses, and

--profits on transactions between related organizations.

We made reductions on all of the audits reviewed. Some examples of unreasonable and unallowable costs we identified which neither the intermediary nor HCFA had identified are:

--A facility paid its parent company $28,212 for management services but we saw no evidence that any services had been provided.

--One facility included $29,065 in costs for services provided to hospitalized patients. The hospitals were billed for these services and the hospital can include these charges in its costs for Medicare reimbursement purposes. Permitting the facility to include these costs would amount to duplicate payment--once to the facility and once to the hospital. Several other facilities also included the same type of costs.

--A facility owner was paid $11,856 in excess salary.

--A facility paid a related organization $5,430 more to sublease a building than the related organization paid to lease it.

Some of the intermediary auditors were more successful than others in identifying unallowable costs, however, we generally found similar deficiencies in the audits performed by each of the five intermediaries whose audits we reviewed. These five intermediaries performed 24 of the 38 independent facility audits.

Perhaps of more interest than the unallowable costs we were able to identify by reviewing the intermediaries' workpapers were the questionable costs where the documentation in the workpapers was insufficient for us to determine how much cost should be eliminated. Most of these costs related to transactions between 12 of the facilities and organizations which we considered related to the facility by common ownership or control. Medicare cost reimbursement principles permit reimbursement for such transactions at the lower of (1) the cost incurred by the related organization in furnishing the supplies or services or (2) the costs at which the supplies or services could be obtained elsewhere (see 42 CFR 405.427). About 60 percent of the related organization transactions were for purchases of supplies, and the remainder were primarily for management and administrative services. The costs of these supplies and services in most cases amounted to more than 40 percent of the facilities' total reported costs. Attachment II summarizes the total costs reported by the facilities and shows our estimate of the portion of the costs represented by related organization transactions. Examples of these related organization transactions are:

--A facility purchased $413,539 worth of supplies from a related organization. The related organization was not audited and no adjustments were made to eliminate any profits or unallowable costs.

--Another facility purchased $1.6 million worth of supplies and services from a related organization. This facility routinely marked-up supplies provided to home patients. In 1978, the mark-up was 10 percent (increased to 35 percent in 1981). Any intercompany profits or unallowable costs were not eliminated because the related organization was not audited.

--A facility was allocated $101,790 for services provided by the regional office of the parent company, a chain organization. The auditors eliminated $4,322 of this amount based on an error in the amount allocated. The remaining $97,468 was unaudited.

The data reviewed did not provide enough information to enable us to determine how much of the related organization costs were audited by the fiscal intermediaries. However, none of the audits determined the actual costs to the related organizations selling dialysis supplies or the costs at which the supplies could be obtained from nonrelated organizations. Also, in many instances, home office and regional office costs reported by chain facilities were not audited. Therefore, substantial portions of costs were included in the cost reports HCFA used without adequate assurance of compliance with Medicare regulations concerning related organization costs.

We did obtain some information which indicates the extent of unallowable or unreasonable costs included in some related organization transactions. One facility covered by our review which belonged to a large national chain had related organization costs of about $540,600, including home office expenses of about $124,400. This amount was part of about $10.3 million in home office expenses the parent company allocated to its ESRD facilities for the year. HCFA designated a separate intermediary to audit the parent company home office costs. As part of our analysis, we reviewed the report and related working papers for this audit and found the audit to be insufficient.

We discussed this audit with intermediary officials. One of the officials advised us that no effort had been made to determine if the home office costs were reasonable or if the costs were related to patient care. He advised us also that HCFA had not authorized enough time to conduct an adequate audit and they only eliminated the obvious costs which were specifically unallowable under Medicare regulations. For most of the $10 million home office expenses the auditors simply verified that the amounts reported agreed with the amounts shown in the parent company's general ledger. We believe that this home office expense audit cannot reasonably be used to determine the cost of dialysis treatments. Five of the 13 facilities whose audits we reviewed were part of this chain. All had essentially the same arrangements with related organizations.

The Inspector General's Office for the Department of Health and Human Services recently completed a review of the 1977 and 1978 costs reported by one of the facilities in this chain. Their review showed that

--this facility had paid about $309,000 or 149 percent more for property and equipment leased from a related organization than it would have cost to own the same property and equipment,

--the facility was charged 22 percent more by a related supply company for certain routine dialysis supplies than the related organization had charged three unrelated facilities in the same geographical area, and,

--in some instances, the facility paid up to 56 percent more for supplies purchased from the related organization than would have been paid had the supplies been purchased from unrelated vendors.

Another facility which is part of another chain paid a related organization about $199,300 for dialysis supplies which amounted to about 39 percent of the facility's total operating costs. Unlike most of the audits we reviewed, the intermediary auditors for the facility tried to eliminate the related organization profits for these transactions based on a profit percentage computed from the related organization's unaudited financial statements. Intermediary officials told us that their $32,735 adjustment did not eliminate all profits involved, but it was the best adjustment they could do since the related organizations would not allow them to review pertinent invoices.

The related organization that provided the dialysis supplies to the facility reviewed, held the master lease on the facility, and owned the facility's dialysis machines. We believe that a full audit of this organization's costs probably would have disclosed significant amounts that were unreasonable or not related to patient care. For example, we noted that in 1979, the organization spent $163,000 for five Mercedes Benz sports cars—one for use by each of the five physician owners.

In addition, this related organization was managed and operated by employees of four of the ESRD facilities controlled by the owners of the related organizations which had no employees of its own. The organization paid the facilities $36,000 for the services of these employees. The intermediary auditors eliminated $36,000 from the facility's cost report based on the amount of time that the facility employees stated was devoted to operating the related organization. The intermediary auditors told us that they believed the adjustment was reasonable since it equaled the amount paid. We believe that the true cost of operating the supply and leasing business could have been significantly more than the $36,000 eliminated and should have been audited. There was not enough information available for us to determine the actual expenses incurred by the facilities to operate the related organizations.

We are presenting this information to provide a general idea of the extent of related organization transactions. The HCFA audits generally did not eliminate related organizations' profits or unallowable costs. Intermediary officials told us that they were not provided enough time or financial resources to audit the cost of related organizations. We believe that the audits should have been expanded to include reviews of related organizations' activities so that unallowable profits and costs not related to patient care could have been identified and eliminated.

The audits should also have included some market surveys to determine the costs that the goods and services could have been obtained from unrelated organizations. Since such review procedures were not followed we question whether the audit results should be used as the primary basis for establishing prospective reimbursement rates.

PHYSICIAN COMPENSATION

As part of our analysis of the 13 facility audits we obtained some information on the amount of compensation and other benefits several physicians receive through the ESRD program. Medicare regulations allow physicians to select one of two reimbursement methods for their ESRD services, the initial and the alternative methods. Under the initial method, reimbursement for physicians' routine supervisory patient care is made to the facility as part of the facility's reimbursement rate. The facility then reimburses the physician for his/her services. Non-supervisory services are billed separately and paid on a fee-for-service basis. Physician services provided to home patients are billed on a fee-for-service basis. Under the alternative reimbursement method, the physicians are paid a comprehensive monthly fee by Medicare for supervisory services provided to both in facility and home patients. HCFA has set a maximum reimbursement rate for services provided to in facility patients at $260 per month and $182 per month for home patients. Each carrier establishes monthly reimbursement rates for the physician in its service area subject to the limits set by HCFA. Under HCFA's proposal, all physicians would be paid under the alternate method and would be paid the same amount for infacility and home patients--an average of about $184 per month per patient.

Although there are some limits on the amount Medicare will reimburse for some ESRD services, there is no overall limit on the amount of compensation, benefits, or profits that physicians can receive under the ESRD program. Some of the information we were able to obtain on physicians' compensation and other benefits shows that some physicians received significant amounts of compensation or monetary benefits through the ESRD program. Generally, payments to physicians for administrative services and profits would be included in the facility cost reports. Some examples follow.

The physician owner of a relatively small ESRD facility received about $96,000 in a 1-year period from the facility for administrative services, even though the facility had a non-physician administrator, an assistant administrator, and a chief of nursing services. During the same period, the physician received about $57,400 from the Medicare program under the alternative reimbursement method. The physician also sub-leased the building to the facility and received dividends as its majority stockholder. In addition, the physician maintained a full-time medical practice from which he received Medicare payments of about $44,500 for non-ESRD services.

Two owner physicians of another facility received during a 1-year period combined compensation of

--$192,000 from the facility for administrative services;

--$132,000 from Medicare under the initial method of reimbursement for supervisory services; and

--$186,000 from the facility in profit sharing dividends.

A physician employee of another facility received during a 1-year period

--$56,000 for administrative services;

--$121,900 from the Medicare carrier for supervisory services;

--free hospitalization and professional liability insurance;

--the use of 1,000 square feet of space at $10 a month for his private medical practice; and

--about $25,000 from Medicare for non-ESRD related services.

The nation's largest ESRD chain organization paid more than $5.3 million in 1978 to some of the physicians or groups of physicians who operated its facilities. The payments were made for administration of the facility and/or under profit sharing agreements and were generally based on the facilities' profits. The payments were made by the home office and charged back to the facilities through the allocations of home office expenses. The average payment was about $69,000 and ranged from less than $100 to $360,000.

The intermediary auditors did not determine the reasonableness of these payments. The payments were included as part of the facilities' total operating costs which were used to establish the proposed new reimbursement rates. Ten of the 38 independent facilities audited were part of this chain.

MEDICARE HOME DIALYSIS COSTS

HCFA estimated nationwide the weighted median home dialysis per treatment costs for hemodialysis to be $87; $114 for CAPD; and $111 for IPD. We estimated that for the 13 States covered by our review the weighted mean home dialysis per treatment costs to be $103, $110, and $134, respectively. The methodologies used by HCFA and GAO to estimate home dialysis costs differ significantly and would be expected to result in somewhat different cost estimates.

HCFA reviewed home costs for 2,232 patients who obtained their supplies and equipment primarily through one of 23 selected facilities or two State kidney programs. We reviewed home costs for 656 patients randomly selected from the universe of patients in 13 States regardless of their source of supplies and equipment. The majority (70 percent) of our sample patients obtained their supplies and equipment on their own. Theoretically, we would expect that patients obtaining supplies through a facility, as HCFA's sample patients did, should obtain them at a lower cost because of the advantages of volume purchasing by facilities and hospitals. This could help explain part of the differences between the HCFA and GAO estimates. Because HCFA proposes to use a combination rate covering both home and in facility patients, it probably is more appropriate to use a sample like HCFA's because under the proposed rates most home patients are expected to obtain their supplies through the facility.

HCFA made certain assumptions in developing its estimate of home dialysis costs at the 25 selected locations. While we did not have an opportunity to review all the assumptions HCFA made, we did look at those for the Maryland Kidney Disease Program because the supply costs HCFA found were only about half of what we found. Of HCFA's sample, 107 patients were from the Maryland Kidney Disease Program. To determine the number of home patients in the Maryland program and the number of home treatments they received, HCFA apparently assumed that the

--number of home patients in the program at year-end represented the average number of home patients for the year,

--home patients had dialyzed at home all year without any in facility treatments during the year, and

--home patients obtained all their supplies and equipment through the Maryland program.

The data we obtained from the Maryland program for 1980 show that this was generally not the case. Several of the Maryland program home patients were not getting all their supplies and equipment through the program. Some were getting only drugs and water treatment services. Others were getting only part of their supplies and/or equipment from the program. Our data indicate also that some of the patients were hospitalized or otherwise received in facility treatments during the year. By assuming that the patients got all their services from the program, HCFA's total cost data for patients using the Maryland home program would be understated and by not adjusting for actual time on dialysis or for in facility treatments the number of treatments used to compute average per treatment costs would be overstated. Both of these would result in an understated average cost per treatment.

As HCFA pointed out in the notice of proposed rulemaking, it is not sure that only reasonable and allowable costs were included in its estimate. Although our estimate includes only costs determined allowable by the Medicare contractors, except for the 122 patients obtaining supplies through hospitals where retroactive adjustments could be made, we are not 100 percent sure that we captured all costs.

We would like to make several observations related to the data we obtained. First, we noted wide ranges in the cost per treatment among patients and among the eight ESRD networks covered by our review. Among the networks average cost per treatment ranged from a low of $81 to a high of $124 for hemodialysis, from $96 to $126 for CAPD, and from $92 to $186 for IPD. Among individual patients the ranges were even greater--from $55 to $693 per treatment for hemodialysis, from $46 to $639 for CAPD, and from $56 to $328 for IPD.

A number of factors contribute to the wide ranges including:

--The length of time a patient has been on home dialysis. Patients just beginning generally incur substantial start up costs and, thus, new patients have higher average costs. Conversely, patients who have been dialyzing at home for a long period may have purchased their equipment in previous years and would show no equipment costs.

--Whether patients need special or additional supplies or equipment such as water treatment equipment in areas with hard water or because of complicating medical conditions.

--Whether equipment is owned by the patient or is rented.

--The source used for obtaining supplies and equipment.

HOME DIALYSIS COSTS COULD PROBABLY BE SUBSTANTIALLY LOWERED

Although our cost data for home dialysis treatments is reflective of what Medicare was paying for such services in 1980, we do not believe that it is necessarily representative of the costs that an efficient and economical provider would incur to deliver such services. As discussed below, our data indicate that significant opportunities exist for lowering home dialysis costs.

Comparison of Equipment Rental and Purchase Costs

About 70 percent of our sample patients obtained dialysis machines through rental agreements with suppliers or the patients' supporting facility. To determine if savings could be realized by purchasing these machines we compared data from four major equipment manufacturers on purchasing, maintaining, and renting their equipment. The data provided covered eight different machines used by home patients. The prices quoted ranged from $6,650 to about $10,030 per machine. Monthly rental charges which generally included maintenance ranged from $370 to about $525. Maintenance contracts ranged in price from $645 per year to about $1,100.

Using this data we computed the difference between purchase and rental costs for a five-year period, the estimated useful life for the machines. Our computations for these eight machines showed that the average costs of purchasing would be about $15,800, or about $3,200 a year less than renting it. This equates to a difference of about $20 a treatment. Savings ranged from $11,800 to $21,900.

We visited three VA hospitals to get information on their methods of providing dialysis equipment to home patients. The three hospitals purchased the dialysis machines used by their home patients as a cost saving measure. An official at one hospital advised us that this method enabled VA to reissue available equipment to new patients or to transfer it to or from in facility use as the needs demanded. The official said that by owning and properly maintaining their equipment it had lasted well beyond the useful life stated by the manufacturers. He advised us also that there was little administrative burden associated with the management of the equipment once it entered their inventory.

Reasonable Charge and Reasonable Cost Determinations

Suppliers that provide dialysis equipment and supplies for ESRD home patients are generally reimbursed by Medicare carriers on the basis of the reasonable charge for such services. ESRD facilities that choose to provide such services for their home patients are usually reimbursed through an intermediary on the basis of reasonable costs. For those home patients for whom we had both the billed and allowed amounts for dialysis equipment and supplies we determined the reduction made to the amounts billed. The data showed a total of about $6 million billed for supplies and about $1.3 million for equipment. These amounts were reduced by the carriers and intermediaries to about $5.8 million for supplies and $1.2 million for equipment for an average reduction of about 3 percent for supplies and 10 percent for equipment. Data published by HCFA on reasonable charge reductions shows that the average reasonable charge reduction for calendar year 1980 for all part B claims was about 22 percent.

Although our costs reflect virtually no reasonable charge reductions for supply charges, we noted large differences in the amounts charged per treatment by different suppliers. For example, for hemodialysis patients, average supply costs ranged from a low of $72 for one supplier to a high of $114 for another. Similar ranges were from $99 to $163 for CAPD and from $67 to $180 for IPD.

About 120 of our sample home patients were getting their supplies through hospitals. Hospital costs are subject to retroactive adjustments based on annual audits. Our computation of the reasonable cost reductions for the hospitals servicing these patients could be over or understated to the extent that retroactive adjustments are made.

Variation In Machine Rental

As previously stated, about 70 percent of our sample patients were using rented dialysis machines obtained either through their support facility or directly from a supplier. The data analyzed to date show monthly allowed amounts for machines used by hemodialysis patients ranged from $34 to $648. Those allowed for machines used by IPD patients ranged from $125 to $440 per month. The range of machine rental charges allowed for the major sources used were as follows:

Source of Machines	Range of Monthly Rentals Allowed
Hemodialysis patients	
Independent facilities	$100 - $615
Hospitals	34 - 439
Cobe	205 - 364
Extracorporeal	192 - 388
Cascade-Drake	165 - 409
Cordis Dow	330
Baxter Travenol	156 - 400
Organon Teknika	181 - 439
Dialysis Inc.	400 - 648
IPD Patients	
Amer. Med. Prod.	125 and 160 (note a)
Hospital	200
Erika	125 and 160 (note a)
Cascade-Drake	322 - 346
Physio Control	407 and [illegible]0 (note a)

a/ The higher allowed amounts resulted primarily from a price increase made during the year.

The data available in most instances did not contain information on the rental agreements between the equipment suppliers and the ESRD facilities or patients or specific information on the types and capabilities of rental machines. Therefore, we could not determine to what extent cost differences could be due to the different prices paid for similar machines. Several other factors could account for some or all of the differences. For example, rental rates would vary depending on

--whether or not the monthly charges cover maintenance and repairs,

--whether or not the different machines have the same capabilities,

--the types of optional or auxiliary equipment included in the agreement, and

--whether or not provider facilities add a surcharge to the suppliers' equipment charge and the amount of the surcharge.

Surcharges

Several of the independent facilities and hospitals providing equipment and/or supplies for their home patients added a surcharge for their services to the costs at which they obtained the items. The data analyzed to date show that 9 of 12 providers were marking up equipment and/or supply bills by amounts from 10 to 45 percent of their costs. One facility added a flat $25 charge per supply order. Another facility added the lower of $55 or 55 percent to each order, usually $55. Other facilities which provided this service did not charge for it.

Two of the hospitals that added a surcharge for supplies received the bulk supplies and redistributed them to their home patients. Three others merely ordered the supplies and processed the claims. The supplies were shipped directly to the home patients. We do not have enough information to determine the arrangements used by the remaining providers.

ESRD NETWORKS

The 1978 Amendments provided for the establishment of renal disease network organizations as a means of assuring effective and efficient administration of ESRD Medicare benefits. A total of 32 network organizations were established to cover all geographic areas of the country. Membership in these organizations is generally made up of representatives from each of the ESRD facilities within the networks area and consumer representatives. Responsibilities given to the networks included

--encouraging the use of the most effective treatment settings,

--developing criteria and standards for quality and appropriate patient care,

--setting network goals for placing patients in self-care settings and for kidney transplants,

--working with facilities to meet network goals,

--evaluating procedures used by facilities and providers to assess the appropriateness of patients for treatment modes, and

--submitting periodic reports to HHS on goals, performance, and projected service needs.

We made a limited evaluation of the effectiveness of the networks in carrying out these responsibilities. Our evaluation covered 8 of the 32 networks and consisted primarily of

- --reviewing the organizational structure of the networks, annual reports, network policies and procedures relating to goals and objectives, and the criteria and procedures used for their certification of need reviews,
- --discussing network responsibilities and performance with network officials, and
- --obtaining the views of selected facility officials on the effectiveness of the networks.

Our review indicates that most of the networks covered by our review had not met all the requirements of the 1978 amendments. Some appeared to be operating more as data gatherers and reporters than as active participants in the planning and directing of renal disease services within their respective areas. In this respect, the networks were able to provide us much home patient data. The data provided in most instances was not readily available from HCFA.

The organizational structures of the networks reviewed generally conformed with statutory requirements. All had established goals to increase the number of home patients and kidney transplants. Although these goals were met in many instances, many of the goals reviewed were more in the nature of projections based on prior years experiences than attainable objectives the facilities should strive to achieve to increase the use of these two methods of treatments. At the time of our review, most of the eight networks had not developed criteria or standards for quality and appropriateness of care. About half had made efforts to evaluate the patient care provided by the facilities in their area.

All the networks had some procedures for reviewing and evaluating applications for the establishment of new facilities or the expansion of existing ones. The procedures and criteria followed and the extent of coordination with other health organizations varied from network to network. The dispositions made of the applications processed during the period of our review would indicate that the networks' recommendations probably did not have much impact on the final decisions made by HCFA because about 50 percent of the applications disapproved by the networks were approved by HCFA.

We visited 18 facilities in 4 of the 8 networks to obtain the views of facility officials on the effectiveness and usefulness of their networks. The officials from eight facilities in two of the networks were of the opinion that the networks were performing useful functions. However, officials at two of these facilities stated they could get by without the networks. Officials from one of the two other facilities visited in these two networks were of the opinion that the network should not have been established initially because of the conflict of interests involved. Officials at the second facility had no opinions to give since they had had few contacts with the network. The views of the officials from the eight facilities visited in the other two networks were all negative. Officials at four of these facilities thought the networks should be discontinued.

In conclusion, based on the limited work we performed, the networks reviewed do not appear to be very effective in carrying out the objectives of the 1978 amendments. Our conclusion is similar to the views expressed by HCFA officials in testimony before this Subcommittee last September. At that time, it was stated that HCFA had little evidence that the networks had successfully accomplished any of their major functions. In addition, it was stated that few of the networks had had any impact on the quality of care provided. It was stated also that HCFA was not satisfied with the networks' planning activities and that HCFA proposed to eliminate the networks.

COSTS AND NUMBER OF TREATMENTS AS REPORTED BY THE FACILITIES AND AS ADJUSTED AS OF SEPTEMBER 1981 BY THE FISCAL INTERMEDIARY, HCFA, AND GAO FOR THE 13 INDEPENDENT FACILITIES

Facility		Costs	Number of treatments	Average costs per treatment	Per treatment adjustment to reported costs (decrease (increase)) (note a)
Kidneycare of Florida, Clearwater Unit, Clearwater, Fla.	Reported	$ 516,058	4,248	$121.48	
	Intermediary	453,793	4,247	106.85	$14.63
	HCFA	453,793	4,247	106.85	0
	GAO	430,603	4,247	101.39	5.46
Kidneycare of Florida Lakeland Unit, Lakeland, Fla.	Reported	711,662	5,858	121.49	
	Intermediary	565,764	5,671	99.76	21.73
	HCFA	565,764	5,671	99.76	0
	GAO	551,924	5,671	97.32	2.44
Sarasota Artificial Kidney Center, Sarasota, Fla.	Reported	899,502	7,005	128.41	
	Intermediary	821,649	7,005	117.29	11.12
	HCFA	806,085	7,005	115.07	2.22
	GAO	773,006	7,005	110.35	4.72
St. Petersburg Artificial Kidney Center, St. Petersburg, Fla.	Reported	1,155,984	9,499	121.70	
	Intermediary	1,082,859	9,499	114.00	7.70
	HCFA	1,057,984	9,499	111.38	2.62
	GAO	1,018,603	9,499	107.23	4.15
Community Dialysis Services of Northwest Georgia, Rome, Ga.	Reported	574,158	4,972	115.48	
	Intermediary	538,867	4,866	110.74	4.74
	HCFA	538,867	4,866	110.74	0
	GAO	499,210	4,866	102.59	8.15

Facility		Costs	Number of treatments	Average costs per treatment	Per treatment adjustment to reported costs (decrease (increase)) (note a)
Community Dialysis Services of Southwest Georgia, Valdosta, Ga.	Reported	$ 710,837	6,699	$106.11	
	Intermediary	687,013	6,422	106.98	$ (.87)
	HCFA	687,013	6,422	106.98	0
	GAO	619,570	6,422	96.48	10.50
Anderson Dialysis Clinic, Inc., Anderson, S.C.	Reported	662,858	4,341	152.70	
	Intermediary	508,683	4,145	122.72	29.98
	HCFA	458,943	4,145	110.72	12.00
	GAO	435,724	4,145	105.12	5.60
Florence Dialysis Center, Inc., Florence, S.C.	Reported	1,096,007	11,189	97.95	
	Intermediary	939,909	10,623	88.48	9.47
	HCFA	892,464	10,623	84.01	4.47
	GAO	843,240	10,623	79.38	4.63
Florida Parish Artificial Kidney Center, Hammond, La.	Reported	683,690	4,271	160.08	
	Intermediary	588,915	4,271	137.89	22.19
	HCFA	528,607	4,271	123.77	14.12
	GAO	483,532	4,271	113.21	10.56
Cape Code Artificial Kideny Center, Yarmouth, Mass.	Reported	516,752	4,513	114.50	
	Intermediary	505,214	4,513	111.95	2.55
	HCFA	505,214	4,513	111.95	0
	GAO	472,847	4,513	104.77	7.18
Dialysis Services of New Hampshire, Inc., Concord, N.H.	Reported	1,088,134	7,075	153.80	
	Intermediary	980,941	7,188	136.47	17.33
	HCFA	866,152	7,188	120.50	15.97
	GAO	854,261	7,188	118.85	1.65

Facility		Costs	Number of treatments	Average costs per treatment	Per treatment adjustment to reported costs (decrease (increase)) (note a)
Southern Connecticut Out of Hospital Dialysis Unit, Inc., Bridgeport, Conn.	Reported	$1,576,609	11,006	$143.25	
	Intermediary	1,492,696	10,966	136.12	$ 7.13
	HCFA	1,232,666	10,966	112.41	23.71
	GAO	1,230,693	10,966	112.23	.18
The Kidney Center, Boston, Mass.	Reported	5,165,798	46,886	110.18	
	Intermediary	4,786,213	46,515	102.90	7.28
	HCFA	4,768,381	46,515	102.51	.39
	GAO	4,456,291	46,515	95.80	6.71

a/Represents the extent of adjustments beyond those made by the immediately preceding organizations.

TOTAL COST REPORTED AND GAO'S ESTIMATE OF TRANSACTIONS WITH RELATED ORGANIZATIONS FOR THE 13 INDEPENDENT FACILITIES

Facility	Total reported costs	Related organization transactions: GAO estimated costs	Related organization transactions: Percentage of total reported costs
Kidneycare of Florida, Clearwater Unit, Clearwater, Fla.	$ 516,058	$ 286,825	56
Kidneycare of Florida, Lakeland Unit, Lakeland, Fla.	711,662	352,471	50
Sarasota Artificial Kidney Center, Sarasota, Fla.	999,502	415,551	46
St. Petersburg Artificial Kidney Center St. Petersburg, Fla.	1,155,984	540,624	47
Community Dialysis Services of Northwest Georgia, Rome, Ga.	574,158	155,619	27
Community Dialysis Services of Southwest Georgia, Valdosta, Ga.	710,837	212,503	30
Anderson Dialysis Clinic, Inc., Anderson, S.C.	662,858	291,891	44
Florence Dialysis Center, Inc., Florence, S.C.	1,096,007	514,083	47
Florida Parish Artificial Kidney Center, Hammond, La.	683,690	302,166	44
Cape Cod Artificial Kidney Center, Yarmouth, Mass.	516,752	225,956	44
Dialysis Services of New Hampshire, Inc., Concord, N.H.	1,088,134	105,110	10
Southern Connecticut Out of Hospital Dialysis Unit, Bridgeport, Conn.	1,576,609	0	0
The Kidney Center, Boston, Mass.	5,165,798	2,577,169	50

Mr. ZIMMERMAN. I certainly will. To my left is Mr. Tom Dowdal. He is responsible for GAO's work in the medicare area. And to my right is Mr. Joe Daigle, and he was responsible for the GAO work on the audit that we plan to discuss today.

Mr. Chairman and members of the committee, we are pleased to be here today to discuss our ongoing review of reimbursement issues in medicare's end-stage renal disease program. As requested, our discussion will focus on the data used by the Health Care Financing Administration in preparing its recent proposal to establish a prospective reimbursement system for paying for home and outpatient dialysis treatments under the ESRD program. We will also provide some information on physician compensation in the program and briefly discuss the role of the ESRD networks.

In summary, we believe that the data HCFA used, and the resulting proposed ESRD payment rates, probably overstate what it would cost an efficient and economical provider to deliver needed services. In particular, we question the accuracy of the cost data obtained on independent facilities because of the incomplete audits on which the data is based.

HCFA proposes to establish a composite rate designed to cover the cost of both home and in facility dialysis treatments. Each facility will receive a certain payment rate per treatment, adjusted for geographic differences in the cost of labor. According to the proposal, the average payment for independent facilities will be $128 per treatment and $132 per treatment for hospital-based facilities. These amounts will be paid regardless of whether the treatment is furnished in the facility or in the patient's home.

We believe that HCFA's proposed reimbursement system should be based on the costs which would be incurred by an efficient and economical provider to deliver needed services. In order to determine the level at which efficient and economical providers can deliver needed services, we believe it is necessary to obtain through audit data on actual reasonable and allowable costs incurred by a statistically valid sample of providers. To see if HCFA had this data, we reviewed 13 of the 38 audits of independent facility costs which the intermediaries had performed and HCFA used in establishing its proposed rates. We do not believe the audits provided HCFA with the data necessary to adequately establish a prospective reimbursement system because the audits did not result in the elimination from the costs reported by the facilities of substantial amounts of unreasonable and unallowable costs.

The total costs reported by the 13 facilities were about $15.4 million. Work done by the fiscal intermediaries and HCFA resulted in reductions of about $2 million to the reported costs. Based on our limited review, we estimate there should have been additional reductions of about $700,000. The adjustments we made would reduce the average cost per treatment for the 13 facilities reviewed by about $5.50. A more complete audit might have resulted in additional reductions.

We made reductions on all of the audits reviewed. Two examples of unreasonable and unallowable costs we identified which neither the intermediary nor HCFA had identified are an instance where a facility paid its parent company $28,212 for management services, but we saw no evidence that any services had been provided. And in another instance where a facility paid a related organization $5,430 more to sublease a building than the related organization paid to lease it.

Some of the intermediary auditors were more successful than others in identifying unallowable costs; however, we generally found similar deficiencies in the audits performed by each of the five intermediaries whose audits we reviewed. These 5 intermediaries performed 24 of the 38 independent facility audits used by HCFA.

Perhaps of more interest than the unallowable costs we were able to identify by reviewing the intermediaries' workpapers were the questionable costs where the documentation in the workpapers was insufficient for us to determine how much cost should be eliminated. Most of these costs related to transactions between 12 of the facilities and organizations which we consider related to the facility by common ownership or control. The cost of supplies and services obtained from the related organizations in most cases amounted to more than 40 percent of the facilities' total reported costs.

Let me give a few examples of the related organization transactions we observed. A facility purchased $413,539 worth of supplies from a related organization. The related organization was not audited and no adjustment was made to eliminate any profit or unallowable costs.

Another facility purchased $1.6 million worth of supplies and services from a related organization. This facility routinely marked up supplies provided to home patients. In 1978, the markup was 10 percent, and in 1981 the markup was increased to 35 percent. Any intercompany profits or unallowable costs were not eliminated because the related organization was not audited.

The data reviewed did not provide enough information to enable us to determine how much of the related organizations' costs were audited by the fiscal intermediaries. However, none of the audits determined the actual costs to the related organization selling dialysis supplies or the cost at which the supplies could be obtained from nonrelated organizations. Also in many instances, home office and regional office costs reported by chain facilities were not audited. Therefore, substantial portions of costs were included in the cost reports HCFA used without adequate assurance of compliance with medicare regulations concerning related organization costs.

We did obtain some information which indicates the extent of unallowable and unreasonable costs included in some related organization transactions. One facility covered by our review which belonged to a large national chain had related organization costs of about $540,600, including home office expenses of $124,400. This amount was part of about $10.3 million in home office expenses the parent company allocated to its ESRD facilities for the year. However, no effort had been made by the intermediary reviewing the cost to determine if the home office costs were reasonable or if the costs were related to patient care.

For most of the $10 million in home office expenses, the auditor simply verified that the amounts reported agreed with the amounts shown in the parent company's general ledger.

HHS's Inspector General's office recently completed a review of the 1977 and 1978 costs reported by one of the facilities in this chain. Their review showed that this facility had paid about $309,000, or 149 percent more, for property and equipment leased from a related organization than it would have cost to own the same property and equipment; the facility was charged 22 percent more by a related supply company for certain routine dialysis supplies than the related organization had charged three unrelated facilities in the same geographical area; and, in some instances, the facility paid up to 56 percent more for supplies purchased from the related organization than would have been paid had the supplies been purchased from unrelated vendors.

We are presenting this information to provide a general idea of the extent of related organization transactions. The HCFA audits generally did not eliminate related organizations' profits or unallowable costs. We believe that the audits should have been expanded to include reviews of related organizations' activities so that unallowable profits and costs not related to patient care could have been identified and eliminated. The audits should also have included some market surveys to determine the costs that the goods and services could have been obtained from unrelated organizations. Since such review procedures were not followed, we question whether the audit results should be used as the primary basis for establishing prospective reimbursement rates.

Turning now to physician compensation. As part of our analysis of the 13 facility audits we obtained some information on the amount of compensation and other benefits several physicians received through the ESRD program. The physician/owner of a relatively small facility received about $96,000 in a 1-year period from the facility for administrative services even though the facility had a nonphysician administrator, an assistant administrator, and a chief of nursing services. During the same period, the physician received about $57,400 for medicare under the ESRD program. The physician also subleased the building to the facility and received dividends as its majority stockholder. In addition, the physician maintained a full-time medical practice from which he received medicare payments of about $44,500 for non-ESRD services.

The Nation's largest ESRD chain organization paid more than $5.3 million in 1978 to some of the physicians or groups of physicians who operate its facilities. The payments were made for administration of the facility and/or under profit-sharing agreements and were generally based on the facilities' profits. The payments were made by the home office and charged back to the facilities through the allocation of home office expenses. The average payments were about $69,000 and ranged from less than $100 to $360,000.

The intermediary auditors did not determine the reasonableness of these payments. The payments were included as part of the facilities' total operating costs which were used to establish the proposed new reimbursement rates, and 10 of the 38 independent facilities audited were part of this chain.

Concerning home dialysis costs, HCFA estimated nationwide the weighted mean home dialysis per treatment costs for hemodialysis to be $87, $114 for CAPD, and $111 for IPD. We estimate that for the 13 States covered by our review the weighted mean home dialysis per treatment costs to be $103, $110, and $134, respectively. The methodologies used by HCFA and GAO to estimate these costs differ significantly and would be expected to result in somewhat different cost estimates, as they did.

HCFA reviewed home costs for 2,232 patients who obtained their supplies and equipment primarily through 1 of 23 selected facilities or two State kidney programs. We reviewed home costs for 656 patients randomly selected from the universe of patients in 13 States regardless of their source of supplies and equipment. The majority of our sample patients obtained their supplies and equipment on their own. Theoretically, we would expect that patients obtaining supplies through a facility, as HCFA's sample patients did, should obtain them at a lower rate because of the advantages of volume purchasing by facilities and hospitals. This could help explain part of the differences between the HCFA and GAO estimates. Because HCFA proposes to use a combination rate covering both home and in facility patients, it is probably more appropriate to use a sample like HCFA's because under the proposed rates most home patients are likely to obtain their supplies through the facility.

Although our cost data for home dialysis treatments is reflective of what Medicare was paying for such services in 1980, we do not believe that it is necessarily representative of the costs that an efficient and economical provider would incur to deliver such services. Our data indicates that significant opportunities exist for lowering home dialysis costs.

About 70 percent of our sample patients obtained dialysis machines through rental agreements with suppliers or the patients' supporting facility. To determine if savings could be realized by purchasing these machines, we compared data from four major equipment manufacturers on purchasing, maintaining, and renting eight different machines used by home patients. Our computation showed that the average cost of purchasing the machines would be about $15,800, or about $3,200 a year less than renting. This equates to a difference of about $20 a treatment. Savings ranged from $11,800 to $21,900.

We also visited three VA hospitals to get information on their methods of providing dialysis equipment to home patients. The three hospitals purchased the dialysis machines used by their home patients as a cost saving measure.

Several of the independent facilities and hospitals providing equipment and/or supplies for the home patients added a surcharge for their services to the cost at which they obtained the items. The data analyzed to date show that 9 of the 12 providers were marking up equipment and/or supply bills by amounts of 10 to 45 percent of their costs. Other facilities which provided this service did not charge for it. Two of the hospitals that added a surcharge for supplies received bulk supplies and redistributed them to their home patients. Three others merely ordered the supplies and processed the claims. The supplies were shipped directly to the home patients. Elimination of unreasonable surcharges would help lower home dialysis costs.

The 1978 amendments provided for the establishment of renal disease network organizations as a means of assuring effective and efficient administration of the ESRD benefits. Responsibilities given to the networks included encouraging the use of the most efficient treatment settings; developing criteria and standards for quality and appropriate patient care; setting network goals for placing patients in self-care settings and for kidney transplants; working with facilities to meet network goals; evaluating procedures by facilities and providers to assess the appropriateness of patients for treatment modes; and submitting periodic reports to HHS on goals and performance and projected service needs.

We made a limited evaluation of the effectiveness of the networks in carrying out these responsibilities and concluded that they do not appear to be very effective. Our conclusion is similiar to the views expressed by HCFA officials in testimony before this subcommittee last September.

Mr. Chairman, this concludes our statement. And we will be glad to answer any questions you or other members might have.

Senator DOLE. Thank you very much, Mr. Zimmerman. It is obvious that this program is riddled with problems that we are going to have to address. It is a program that is almost out of hand and apparently very little effort is made to contain the costs of the program, whether by free-standing clinics, or physicians, or whatever. I note that in one case five Mercedes-Benz's were purchased for some of the physicians, and I assume this is just the tip of the iceberg if we really dug into some of the waste and abuse which indicates a disregard for the American taxpayer. And I can indicate that we do intend to continue this effort, not only in a subcommittee level but in a full committee level. Maybe it is unfair for me to chair the Food Stamp Committee, but as I struggle to take away money from food stamp recipients and see what we are shoveling out to freestanding clinics and physicians and others in this program, I find it hard to comprehend very honestly. So from a personal standpoint, we hope we can help reduce the cost of the program and still protect the patients.

Now, you say that one chain paid $5.3 million to physicians that operated facilities. What service did those doctors provide to earn that amount if those facilities also employed administrators?

Mr. ZIMMERMAN. We could not determine from the information available to use what services that those physicians provided.

Senator DOLE. Are we certain they provided any?

Mr. ZIMMERMAN. That is a question that we cannot determine at this point.

Mr. DOWDAL. Normally those facilities did have administrators separate from the physicians.

Senator DOLE. Well, would a payment such as the $5.3 million to physicians be an allowed cost under medicare?

Mr. ZIMMERMAN. To the extent that the payment represents profit sharing, it would probably not be allowed. If the physicians did in fact perform a service, the payments would be subject to a test of reasonableness under the medicare regulations.

Senator DOLE. As I understand it, there are two ways that physicians are reimbursed, and one way is that they can receive about $260 a month per patient for most of the ESRD services he or she provides the patients. In addition, as you pointed out in your statement, physicians can be paid for administrative services and also receive profit sharing dividends. Based on your review, can you indicate what all that could amount to?

Mr. **Zimmerman**. Well, we did, as I indicated, obtain information on a few physicians, and I think the largest amount that we found dealt with two physicians that owned a small facility, and they each received about $255,000 in compensation.

Senator **Dole**. Does that include their regular practice?

Mr. **Zimmerman**. Let me ask Mr. Dowdal.

Mr. **Dowdal**. That wasn't their non-ESRD practice. They would have gotten additional money from that.

Senator **Dole**. This was just their ESRD practice?

Mr. **Dowdal**. That was just money related to the ESRD practice plus the money they got from owning the facility.

Senator **Dole**. And how much, again, did they earn? Well, they did not earn that much, but how much did they receive?

Mr. **Dowdal**. They received $255,000 each, an average of $255,000 each.

Senator **Dole**. Is there any way to limit that activity?

Mr. **Dowdal**. Under the current reimbursement method, no. It is not considered. Under the new proposed method, there still wouldn't be any specific limits upon compensation that physicians could receive. The only limit would be the $128 per treatment, whatever they could make out of getting that.

Senator **Dole**. Could you indicate why hospital-based facility costs are higher? Is it because they are inefficient? They probably are in many cases, but we pay anyway.

Mr. **Dowdal**. Well, we did not specifically look at the hospital audits that HCFA performed because, well, they really did not audit the hospitals. Since hospitals are normally audited as part of the hospital cost settlement process, basically HCFA only desk reviewed the cost reports for those hospitals included in the ESRD audit. Because HCFA wasn't doing anything different than it normally does, we didn't look specifically into those.

Senator **Dole**. As I understand, you are convinced that even in home dialysis we could sharply reduce costs if we took a look at overcharges on rentals and the wide disparity on the rental of the machines. What did you indicate the disparity was for the same type equipment?

Mr. **Zimmerman**. Mr. Dowdal, could you respond to that?

Mr. **Dowdal**. Well, we looked at purchase versus rental of eight different machines and the average savings from purchase over a 5-year period was almost $16,000, which equates to about $20 a treatment lowering of cost.

Senator **Dole**. Are there any limits on what some machine rental agency can charge? I mean, they can charge anything. Is that it?

Mr. **Dowdal**. It is supposed to be paid under medicare's normal usual and customary charge criteria, reasonable charge. But normally when you are making reasonable charge determinations you have a lot of data from a lot of different sources that you can compare and base reasonable charge determinations on.

Senator **Dole**. But also as I understand, there is an added surcharge in many cases.

Mr. **Dowdal**. Yes. If it goes through a facility it could well have one. But that is more on supplies. In the ESRD area there aren't so many people to compare against, so it is harder to make a reasonable charge determination. Often the carrier involved will only have one or two suppliers to look at to compare and it makes it very difficult to make a reasonable charge determination. They have nothing to compare with.

Senator DOLE. Not enough competition. Is that it?

Mr. DOWDAL. Well, that is one way of looking at it.

Senator DOLE. Well, it would seem to me the usual and customary charge is about to bankrupt the program. So maybe we need to find another way to make certain that the patient is taken care of and not everyone else. Maybe we have been focusing in the wrong area. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman. Mr. Zimmerman, what is the cost to medicare for this program?

Mr. ZIMMERMAN. For 1982, it is estimated at about $1.8 billion.

Senator BAUCUS. $1.8 billion, the estimate for 1982?

Mr. ZIMMERMAN. That is right.

Senator BAUCUS. And how much of the renal dialysis program is paid for by other parties? That is other than medicare. That is, patients and insurance companies or States.

Mr. ZIMMERMAN. Maybe Mr. Dowdal would have some information on that.

Mr. DOWDAL. I think it is over 90 percent of the people getting ESRD services paid by medicare. It is basically either medicare, VA, or the Federal employees health insurance program. And almost everybody is medicare. Those are basically the only programs that pay for it. Under last year's amendment in the Budget Reconciliation Act, the first year of dialysis now is supposed to be covered by private insurance if the patient is covered by that.

Senator BAUCUS. Do any or all of you have any feel for how much we could save or trim off that $1.8 billion if we tightened up the procedures in a reasonable way and yet allow the patients to have the program they are entitled to?

Mr. ZIMMERMAN. I think we would just be speculating.

Senator BAUCUS. That is all I am asking for. Based upon your best guess.

Mr. ZIMMERMAN. Well, in terms of independent facilities we did point out in our statement that just the adjustment that we made resulted in a reduction of $5.50 per treatment. I would not want to suggest that that amount could be projected to the total universe. And that I would say is about the only figure we would have right now.

Senator BAUCUS. And how many treatments a year are there?

Mr. DOWDAL. There is about a total of between 8 and 9 million treatments.

Senator BAUCUS. Eight and nine million treatments?

Mr. DOWDAL. Per year.

Senator BAUCUS. So that would be about 70.

Mr. DOWDAL. Half of those were independent, and we were only dealing with the independents. So if you could project that, which we don't say you can, that would be about between $20 and $25 million.

Senator BAUCUS. Is it your feeling though that there could be a substantial savings, a very substantial savings, or a modest savings? What is your feeling?

Mr. Dowdal. We were not able to address the related organization data, the profits in there.

Senator Baucus. Because of insufficient data? Is that the reason?

Mr. Dowdal. Right.

Senator Baucus. Why are you a little tentative in giving estimates here, because of insufficient data?

Mr. Dowdal. Yes.

Mr. Zimmerman. Well, now, we looked at what the intermediaries did in their audits. We did not conduct our own audits of the related organizations. They did not have enough data for us to tell how much money to take out of those costs.

Senator Baucus. Have you discussed your findings with HCFA?

Mr. Dowdal. Yes, we have.

Senator Baucus. Did they agree with your findings? Did HCFA agree?

Mr. Dowdal. They have not argued with them.

Senator Baucus. They haven't what?

Mr. Dowdal. They haven't argued with me about them.

Senator Baucus. So you take that to mean agreement?

Mr. Dowdal. Yes.

Mr. Zimmerman. We did also discuss our findings with the intermediaries and they basically concurred with what we came up with.

Senator Baucus. Could you have found more savings, or more implied savings, if you had greater opportunities to delve a little bit more deeply into this, that is, greater auditing ability or time or whatnot?

Mr. Zimmerman. Well, we think the intermediaries could have done a more complete job of looking at the related cost aspects. And that was not done. And we think there is an opportunity to come up with a reduction in the rate if the intermediaries go back and do a more complete job auditing the independent facilities' cost, particularly their cost associated with related organizations.

Senator Baucus. Are you suggesting that with more comprehensive analysis here that there could be potentially, in your judgment, greater savings?

Mr. Zimmerman. I think so. As I pointed out in the statement, about 40 percent of the costs to the facilities were costs connected with related organization transactions that were not subject to a complete evaluation. And we think if they are, there could be further reductions in the rates established particularly for the independent facilities.

Senator Baucus. So if I understand your answer, you are suggesting that with even greater examinations of the transactions here that perhaps the cost per treatment could be reduced to even more than $5 in some cases. But you cannot go that far because of insufficient data.

Mr. Zimmerman. I would concur with that. That is correct.

Senator Baucus. Thank you very much.

Senator Dole. How many patients—what is it, 69,000—now receive treatment?

Mr. Dowdal. It is about 60,000 now I believe.

Senator Dole. Sixty thousand?

Mr. Dowdal. In the program.

Senator **Dole**. Now, do chain and related organizations enhance the efficiency and the effectiveness of ESRO facilities in providing renal services or are they simply a mechanism to increase reimbursements?

Mr. **Dowdal**. Chain organizations can help hold down costs through things such as volume purchasing. By pooling a number of places, they can afford to hire more qualified people, better managers, but they can also be used as a means of increasing and maximizing reimbursements. We have done a lot of work over the years related to related organizations and we have often found that chain organizations were used to maximize reimbursements.

Senator **Dole**. Well, is there some authority that is needed or any recommendations you make for legislative authority that would permit us to dig deeper into what appears to be a tragedy for the American taxpayer?

Mr. **Dowdal**. I don't know. From the related organization standpoint, whether to get access to the records or not, whether the intermediaries would have difficulty in doing that or not. If the organizations wanted to contest the access to records, they could, and that could drag out any process of determining the actual allowable and reasonable costs for an extended period of time if they would contest the access to records.

Senator **Dole**. Well, how much would it take dollar-wise, and how much time to expand the HCFA audits to take care of some of the shortcomings that you identified?

Mr. **Zimmerman**. It is hard for us to estimate how long it would take the intermediaries. But I think, if we had to make a rough estimate, we would say it would probably be in the neighborhood of 8,000 staff days of audit effort. The length of time it would take to do that, as I just mentioned, would depend a lot upon how much difficulty they have in gaining access to those records to enable them to do the related organization audits. Also, as you know in the last couple of years, the audit budgets for the intermediaries have been cut significantly and they have lost some auditors. So they may not have enough auditors where they could go in and do it in a hurry now because of the decreased number of auditors they have.

Senator **Dole**. Well, maybe we can sell those five Mercedes and hire back one of the auditors. It is a step in the right direction. We will have some additional questions.

[The answers to Senator Dole's questions were subsequently supplied:]

Question 1. HCFA did not, according to testimony presented, determine median cost by dividing total costs by total treatments. Instead, HCFA gave each facilities' cost per treatment equal weight. How was your finding of $5.50 per treatment computed? What would your finding amount to if it was computed on the same basis as HCFA's?

Answer. Our $5.50 per treatment reduction was computed by dividing the total amount of the additional cost reduction which we believe should have been made by the total number of treatments given by the 13 facilities involved. If the amount of our finding had been computed on the same basis as HCFA used, the average amount of reduction in the median cost for the 13 facilities would have been about $5.95 per treatment.

Question 2. Seventy percent of the home patients in your sample bill Medicare directly through carriers for their equipment and supplies. Can we expect these patients to turn to facilities for home dialysis support under the proposed reimbursement scheme? If they do not and a substantial percentage of home patients continue to deal directly with carriers, what might be the result?

Answer. We cannot predict how many patients currently dialyzing at home would switch from obtaining their equipment and supplies directly to obtaining them through a facility. However, any patient currently paying less than $128 for equipment and supplies would incur increased coinsurance costs by switching. We also cannot predict which method new patients will elect.

If significant numbers of patients continue to obtain supplies and equipment on their own, the issues of equipment rental versus purchase, reasonable charge reductions, and wide variations in charges as discussed in our statement would probably continue.

Question 3. Based on your review of independent facilities, HCFA's average cost is overstated by $5.50 per treatment. If we accept that finding as being applicable for all independent facilities, what is the net affect if HCFA reimburses independent facilities at the proposed rate?

Answer. About 8 million dialysis treatments per year are currently being provided. About half of the treatments are provided by independent facilities so each $1 reduction in the rate they are paid under the proposed system would result in a savings of about $4 million. Thus, if our $5.50 reduction for the 13 independent facilities were applicable to all independent facilities, HCFA would be paying about $22 million more than necessary under its proposed rates for independent facilities. Of course, our reduction cannot be statistically projected to other facilities. In addition, we do not claim, nor do we believe, that we eliminated all excess costs from the 13 facilities because of the unresolved questions pertaining to the related organization transactions.

Question 4. According to the HCFA audits hospital-based facility costs are higher than those of independent facilities. Some of this is due to the way overhead is allocated under Medicare. Perhaps some of the difference is due to the treatment of sicker patients. Is there any other mechanism that could explain why hospital-based facility costs are higher?

Answer. Medicare's reimbursement system for hospitals can provide hospitals with incentives to shift costs out of cost centers with specific reimbursement limits, such as those related to routine services. Hospitals can also shift costs to centers covering services highly used by Medicare patients. To the extent that such cost shifting occurs, it would affect overall reported hospital costs for Medicare. However, we do not know to what extent, if any, such costs shifting is occurring.

Senator Dole. Senator Baucus, do you have any more questions?

Senator Baucus. No. Well, I will just follow up slightly. The chairman asked a key question, and that is, what recommendations do you have? I mean, are there insufficient penalties here or are penalties sufficient or what do we do here? There has got to be some way to stop this.

Mr. Dowdal. Well, Senator, since this program began payments have been based upon charges and not upon cost. Now, this is the first attempt in the program's history to base the payments to the facilities on cost. So HCFA did not have this data before. Now, when they went out and got the data, we don't think they did a sufficient job. From our viewpoint, when you are looking at this program, you have to look at it in perspective. Last year you passed a law directing HCFA to establish a perspective reimbursement system effective last October. So it has been almost 6 months since then and it is still not in place. We now have a screen of $138. With the new proposal it would be $128. Obviously, we would rather pay $128 than $138. And we feel that $128 is still above what is required for the independent facilities, for an efficient and economical independent facility. So if we had to make a recommendation, it would probably be along the lines of getting HCFA to issue in final form the new rate of $128, and at the same time go out and redo these audits and get them done right. And as soon as possible revise the rates based upon the new data, which under their proposal they would not have to get comments on again if all they were doing was revising the rates based upon new data. So a combination of those two things, issuing the regulations now because you are going to have to handle methodological comments anyway and then revising it as soon as possible based on better data.

Senator **Baucus**. I appreciate that. I don't know whether this will be helpful, but did you interview patients at all when you did this examination?

Mr. **Dowdal**. We really did not. We did talk to some patients about where they got their supplies and that because it was the only way we could find out. We had a lot of trouble finding where people got supplies. We were running all over the country trying to determine that. We did not really discuss it with the patients.

Senator **Baucus**. Thank you very much.

Senator **Dole**. There was one chain that said they were going to sell off 60 clinics since things were so bad. Did you get into that at all?

Mr. **Zimmerman**. No; I don't think we did. Maybe Mr. Daigle can respond to that.

Senator **Dole**. Are they all operating at a terrific loss these days?

Mr. **Zimmerman**. Were any of our patients that we dealt with in these facilities?

Mr. **Daigle**. I am not sure what the question is, but if the question is were any of our facilities affected by the change, yes. Does that answer the question?

Senator **Dole**. Not really, but it is close enough, because we are talking about the same program. But I was curious. There has been some indication that one of the chains was going to have to sell off 60 clinics if the rate was changed because it would lower their profits. In fact, they would lose money. I don't see how anybody could lose money in this program.

Mr. **Daigle**. Senator, in the 13 audits that we looked at, 5 of the facilities—5 of the 13—belong to the chain.

Senator **Dole**. Are they losing money?

Mr. **Daigle**. Well, I cannot say whether or not. We did not try to determine whether or not they were losing money.

Senator **Dole**. Had you determined what their costs were?

Mr. **Daigle**. No, we did not set that up.

Mr. **Dowdal**. Well, we did look at what their costs were and they were below what the, you know, HCFA came out with an average of $108 and we took $5 off of that.

Senator **Dole**. So you figure their cost is about $102.50?

Mr. **Dowdal**. That would have been about the average, right. And they would be getting $128 on the average nationwide.

Senator **Dole**. That would be a fair profit, wouldn't it?

Mr. **Dowdal**. Yes; that is a pretty good profit, to me anyway.

Senator **Dole**. Well, we may have some additional questions. I am not asking you to stay, but there are a number of additional witnesses. And Senator Durenberger may want to submit some questions in writing as I do. We appreciate very much your testimony.

The next witness is Hon. Richard Kusserow, Inspector General, Department of Health and Human Services. I am happy to have Mr. Kusserow before our committee again. And I hope you remember the President's words that he wants the Inspectors General "mean as junkyard dogs" as you look into some of the Federal programs and taxpayers who support those programs. And we would be happy if you could summarize your statement and then we would be in a position to ask some questions.

STATEMENT OF HON. RICHARD KUSSEROW, INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. KUSSEROW. Just for the sake of brevity I would like to summarize the statement. I would also like to introduce at this time today Larry Simmons, who is the Associate Director for our Office of Audit. To his right is Bill Eichelman, who is Chief of our medicare audit branch.

Mr. Chairman, since 1973 medicare has limited the allowable charges for outpatient dialysis by freestanding charge-based dialysis facilities to $138 per treatment. The $138 limit per dialysis treatment was also applied to hospitals, that is, the program would pay 80 percent of the hospital's actual cost of providing outpatients dialysis treatments, not to exceed the $138. The limits were applied uniformly across the country. They are still in effect today, except for case-by-case exceptions. Exceptions to the limits are granted if a facility can document that its cost of furnishing dialysis care justifies an increase. On the other hand, these reported costs by charge-based facilities were initially viewed by the Health Care Financing Administration as not subject to the provider cost principles. They were generally accepted without field audit and were used as the basis for granting exceptions to the limits.

In June 1978, Public Law 95-292 amended the medicare law. This legislation required the Secretary to have in place by July 1, 1979, not only a system to determine the costs incurred by hospital and independent facilities, but also an incentive reimbursement system to encourage more efficient delivery of services.

In July 1979, we reported to HCFA certain cost overstatements found during an audit of a propriety freestanding facility. We believed it was likely that similar overstatements would exist in the data submitted by other facilities. Also, we cautioned HCFA against using unaudited data reported by dialysis facilities in setting the national incentive rate(s).

In the fall of 1979, HCFA had its intermediaries perform 24 pilot surveys of dialysis facilities. These reviews were undertaken to develop a methodology for planning and implementing an incentive rate mechanism.

Simultaneously, we began to monitor HCFA's efforts to construct an incentive rate, and from time to time we offered advice. As a result of our involvement in HCFA's early planning efforts, HCFA agreed (1) that reliance could not be placed on costs routinely reported by freestanding facilities as a basis for the formulation of the rates; (2) that additional cost data had to be obtained from these facilities that did not report their costs; and (3) that audited cost data had to be used from a statistical standpoint of the entire universe of both hospital-based and freestanding facilities.

In 1980, HCFA selected a statistical sample of 110 dialysis facilities whose costs and related data would be used to construct the incentive rates. Forty of these were freestanding facilities whose reported costs were to be audited by intermediary audit teams. The costs of the remaining 70 hospital-based facilities were to be reviewed by the intermediaries, reconciled to the medicare annual hospital cost reports, and field audited only if necessary. HCFA planned to allow only 80 hours, and 150 hours respectively, for the review of each of the sample provider-based and freestanding facilities, that is, a survey-type review rather than a full audit.

In January of the same year we sent a priority audit memorandum to the Administrator of HCFA outlining the difficulties HCFA was experiencing in implementing the incentive reimbursement system. We expressed our concern about the adequacy of the planned audits and suggested that continuous management attention was needed until the incentive reimbursement system was in place and functioning. HCFA agreed with us that a best effort was needed, but it did not prescribe full-scope audits of the 110 sample facilities. The intermediaries made their reviews and reported the requested cost and treatment data back to HCFA. For the most part, the intermediaries did not render an opinion on the information they furnished. HCFA reviewed and extracted the data necessary to compile a base of information which could be used to develop incentive rate policy and actual rates once final policy was decided upon.

On May 28, 1981, HCFA requested our advance review of the proposed notice for establishing the ESRD incentive rates. Briefly, HCFA used the data from the field reviews to establish a single rate methodology based on the experience of the audited independent facilities. The base rate was set at $130 per treatment, that is, 120 percent of the median of the allowable costs per treatment of the independents.

On June 25, 1981, we replied to HCFA that, for a number of reasons, it was unlikely that the proposal would produce the anticipated $105 million in cost savings. We recommended that HCFA revise its savings estimates and consider certain policy alternatives based upon the more realistic estimates. On July 9, we formally nonconcurred. Our view then, as now, is that the incentive rates should produce a substantial savings as compared to what the program would have spent under the present system.

On August 13, 1981, the Omnibus Reconciliation Act of 1981, Public Law 97-35, became law. Whereas, HCFA's then-proposed incentive rate system was based on a single rate derived from data on free-standing facilities only, section 2145 of the act now required HCFA to develop prospective reimbursement rates for outpatient maintenance dialysis that promotes home dialysis. It further requires the use of either separate composite rates for provider-based and independent facilities to reimburse for home and in facility dialysis or some other method that, after detailed analysis, is determined to be more efficient and to be more effective in promoting home dialysis.

HCFA had previously gathered the data it needed on the cost of in facility outpatient dialysis, but it had no data on the facility costs of home dialysis. HCFA needed to obtain this data quickly in order to move forward timely with the revised incentive rate proposal. On August 5, 1981, HCFA requested our assistance in gathering the needed information. HCFA selected 25 dialysis facilities for survey and worked up an instruction and reporting package which I sent to our field auditors. Our field auditors performed these surveys on a priority basis, and on September 9, 1981, we sent the results of the last completed survey to HCFA.

On November 12, 1981, we commented on a HCFA decision memorandum to the Secretary outlining two options as to how to proceed with the incentive rates. We disagreed with both options for two reasons. One, we believed that HCFA's proposals would not result in the dual rate structure required by the law, but rather in a single rate for independent facilities with an arbitrary adjustment for hospitals. And, two, based upon the available cost data, we believed that the rates being proposed under either rationale would, on the one hand, unfairly penalize hospitals by not giving sufficient recognition to the cost data collected, and, on the other hand, result in undue enrichment of the independents. In effect, we believed that any savings realized from the hospitals would be shared with the independents.

After considering all of these factors involved, HCFA proposed the second option as the proper one and proposed regulations for these incentive rates which were published on February 12, 1981.

This concludes my prepared testimony, and I am prepared to answer questions that you or members of the committee might have, Mr. Chairman.

[The prepared statement follows:]

STATEMENT BY

RICHARD P. KUSSEROW

INSPECTOR GENERAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman and Members of the Subcommittee, we are pleased to appear today to discuss the involvement of the Office of Inspector General in the Medicare End-Stage Renal Disease (ESRD) program. Our testimony discusses our work on the Dialysis Incentive Reimbursement Rates.

Renal Dialysis Incentive Rates

Since the inception of this program, both the numbers of beneficiaries and the program's cost have increased dramatically. Total program costs have risen from about $228 million in 1974 to an estimated $1.5 billion in 1981. The average ESRD patient now consumes over 40 times as many Part B benefits as the average Medicare beneficiary, and about 4 times as many Part A benefits.

Since 1973, Medicare has limited the allowable charge for outpatient dialysis by free-standing charge-based dialysis facilities to $138 per treatment. The $138 limit per dialysis treatment was also applied to hospitals - i.e., the program would pay 80 percent of a hospital's actual cost of providing outpatient dialysis treatments, not to exceed $138 per treatment. The limits were applied uniformly across the country. They are still in effect today, except for case-by-case exceptions. Exceptions to the limits are granted if a facility can document that its cost of furnishing dialysis care justifies an increase. On the other hand, these reported costs by charge-based facilities were initially viewed by the Health Care Financing Administration (HCFA) as not subject to the provider cost principles. They were generally accepted without field audit and were used as the basis for granting exceptions to the limits.

In June 1978, Public Law 95-292 amended the Medicare Law. This legislation required the Secretary to have in place by July 1, 1979, not only a system to determine the costs incurred by hospital and independent facilities, but an incentive reimbursement system to encourage more efficient delivery of services. The Law provided that the incentive rates could be determined either on a cost-related or on some other economical and equitable basis. HCFA chose to develop the rates on a cost-related basis.

Our initial involvement with this program began a year after this office came into existence. In July 1979, we reported to HCFA certain cost overstatements found during our audit of a propriety free-standing dialysis facility. We believed it was likely that similar overstatements would exist in the data submitted by other facilities. Also, we cautioned

HCFA against using unaudited data reported by dialysis facilities in setting the national incentive rate(s).

In the Fall of 1979, HCFA had its intermediaries perform 24 pilot surveys of dialysis facilities. These reviews were undertaken to develop a methodology for planning and implementing an incentive rate mechanism.

Simultaneously, we began to monitor HCFA's efforts to construct the incentive rates and, from time to time, we offered advice. As a result of our involvement in HCFA's early planning efforts, HCFA agreed:

- that reliance could not be placed on costs routinely reported by free-standing facilities as a basis for the formulation of the rates;
- that additional cost data had to be obtained from facilities that did not report their costs;
- that cost data had to be used from the entire universe of both hospital-based and free-standing facilities;
- to base the rates on the costs of a statistical sample of providers and facilities;

- to have audits performed on the costs reported by the statistical sample of facilities and providers.

In 1980, HCFA selected a statistical sample of 110 dialysis facilities whose costs and related data would be used to construct the incentive rates. Forty (40) of these were free-standing facilities whose reported costs were to be "audited" by intermediary audit teams. The costs of the remaining 70 hospital-based facilities were to be reviewed by the intermediaries, reconciled to the Medicare annual hospital cost reports, and field-audited only if necessary. HCFA planned to allow only about 80 hours and 150 hours, respectively, for the review of each of the sample provider-based and free-standing facilities, i.e., a survey-type review rather than an audit.

In January of the same year, we sent another Priority Audit Memorandum to the Administrator of HCFA outlining the difficulties HCFA was experiencing in implementing the incentive reimbursement system. These included:

- unclear and shifting lead responsibility for the project;

- past indecision on the methodology to be used to establish the incentive rates;

- indecision in formulating a plan to scientifically sample facilities whose costs were to be audited and used for this purpose.

Moreover, we expressed our concern about the adequacy of the planned audits. We suggested that continuous management attention was needed until the incentive rimbursement system was in place and functioning.

HCFA continued to plan for the survey-type "audits" and, by April 1980, the reviews were underway. HCFA agreed with us that a "best effort" was needed. But it did not prescribe full-scope audits of the 110 sample facilities.

The intermediaries made their reviews and reported the requested cost and treatment data back to HCFA. For the most part, the intermediaries did not render an opinion on the information they furnished. HCFA reviewed and extracted the data necessary to compile a base of information which could be used to help develop incentive rate policy, and the actual rates, once final policy was decided upon.

For a number of overlapping reasons, we did not re-audit a sampling of the intermediaries' reviews:

- The intermediaries have much more on-line experience in auditing providers and with the application of the provider cost principles than do we. This is one of their main functions and we believed that they could probably do the job as well as, or better than, we could within a given time. Over the years, we've reviewed intermediaries' provider audit activities and have generally found them to be quite satisfactory.

- Our re-reviews would have to be deferred until the completion of the intermediaries' reviews. We doubted that the re-reviews would have been timely or useful without further delaying the incentive rates.

- Policy decisions on the structure and detailed composition of the incentive rates were in a state of flux. By the time the results of the field audits were being received, changes in the originally planned rate methodologies were under consideration and, in fact, later adopted. Some of these changes could, and likely would, have a more significant impact on the incentive rate levels than better refined cost data. These policy matters concerned such considerations as the number of rate categories (e.g., hospital-based/independent/urban/rural), the use of the median of costs or some other method, the inclusion or exclusion of lab costs, the costs at the median of facilities vs the cost at the median of treatments -- so forth. These types of factors, then being considered, would now be the prime determinants of the incentive rate levels. In view of this, it appeared doubtful that re-audits could be significantly productive to the process.

- GAO informed us that they were planning to re-audit a sub-sample of HCFA's sample as part of a review of the ESRD program that they were undertaking for the Congress.

However, in early 1981, we did review the survey or "audited" data reported by the intermediaries for consistency, compliance with instructions, and to see that HCFA extracted and accumulated the information correctly. We found no problems.

On May 28, 1981, HCFA requested our advance review of a proposed notice for establishing the ESRD incentive rates.

Briefly, HCFA used the data from the field reviews to establish a "single rate" methodology based on the experience of the "audited" independent facilities. The base rate was set at $130 per treatment (i.e., 120 percent of the median of the allowable costs per treatment of the independents). When applied to each provider or facility, the proposal called for the labor portion of the base incentive rate to be adjusted for an area wage index -- i.e., tailored for each facility to the local labor market. The individualized rate would represent the maximum charge pertreatment to the program by a free-standing facility, and the maximum cost per treatment allowed by the program for a provider.

On June 25, 1981, we replied to HCFA that, for a number of reasons, it was unlikely that the proposal would produce the anticipated $105 million in cost savings. We recommended that HCFA revise its savings estimates and reconsider certain policy alternatives based on these more-realistic estimates. We did not believe that HCFA's proposal would have realized those savings. On July 9, we formally non-concurred. Our view then, as now, is that the incentive rates should produce a substantial savings as compared to what the program would have spent under the present system.

On August 13, 1981, Congress again became an active participant in this program. The Omnibus Reconciliation Act of 1981, (P.L. 97-35) became law. Whereas HCFA's then-proposed incentive rate system was based on a single rate derived from data on free-standing facilities only, Section 2145 of the Act now requires HCFA to develop prospective reimbursement rates for outpatient maintenance dialysis that promotes home dialysis. It, further, requires the use of either:

- composite rates to reimburse for home and in-facility dialysis (separate rates for provider-based and free-standing facilities, each weighted to account for the relative mix of patients on home dialysis and the relative costs of providing home dialysis services); or
- some other method that, after detailed analysis, is determined to be more efficient and to more effectively promote home dialysis.

HCFA had previously gathered the data it needed on the cost of in-facility outpatient dialysis, but it had no data on the facility costs of home dialysis. HCFA needed to obtain this data quickly in order to move forward timely with a revised incentive rate proposal. On August 5, 1981, HCFA requested our assistance in gathering the needed information.

HCFA selected 25 dialysis facilities for survey and worked up an instruction and reporting package which we sent to our field auditors. Our field auditors performed these surveys on a priority basis and on September 9, 1981, we sent the results of the last completed survey to HCFA. While these surveys were not full audits, our field staff completed all the reviews in less than three weeks!

According to HCFA's computation, the median costs per home dialysis treatment were: $87 for Hemodialysis, $114 for Continuous Ambulatory Peritoneal Dialysis, and $111 for Intermittent Peritoneal Dialysis. Weighting these amounts by the estimated relative numbers of patients treated under each of these modes, HCFA computed a weighted median cost per treatment of $97.

On November 12, 1981, we commented on a HCFA decision memorandum to the Secretary outlining two options as to how to proceed with the incentive rates. We disagreed with both options. We believed HCFA's proposals would not result in the dual rate structure required by the law, but rather a single rate for independent facilities with an arbitrary adjustment for hospitals. Based on the available cost data, we believed that the rates being proposed - under either rationale - would, on one hand, unfairly penalize hospitals by not giving sufficient recognition to the cost data collected, and, on the other hand, result in undue enrichment of the independents. In effect, we believed that any savings realized from the hospitals would be shared with the independents.

After considering all the factors involved, HCFA's proposed second option was chosen and proposed regulations for these incentive rates were published on February 12, 1982.

I would like to briefly touch upon several findings from one of our Service Delivery Assessments that may be of interest to you.

Service Delivery Assessment

During the first half of 1980, we conducted a service delivery assessment of the End Stage Renal Disease Program. Assessments are short-term studies of program or program-related issues conducted directly for the Secretary. In conducting this service delivery assessment, our teams visited 14 dialysis facilities in 10 States and spoke with dialysis patients, persons with kidney transplants, medical staff, ESRD network staff and others. This assessment focused on non-hospital dialysis facilities in urban areas. This type of facility now serves about 50 percent of all dialysis patients and is on the increase.

We reported the findings of our assessment to the Secretary in September of 1980. Three of our chief findings were:

- Largely because of the influence of their nephrologist (kidney specialist), most patients dialyze at a facility and seldom switch to home dialysis or undergo a kidney transplant.
- Patients exercise little choice among available dialysis facilities; nearly all use the facility with which their initial nephrologist is affiliated.
- There is no trend towards significantly greater client interest in home dialysis or kidney transplants.

Our recommendations to the Secretary focused on cost restraints and client rehabilitation; that is, on ways of helping dialysis and kidney transplant patients become more self-sufficient in their treatments and daily activities.

This concludes my prepared testimony. I am ready to answer any questions you may have on our role in this program.

Senator **Dole**. You have just indicated that you disagreed with the methodology the Department has proposed because it does not provide a dual rate as required by law. I want to commend you for being forthright in disagreement. I think if in fact there is a disagreement, and you feel your position is justified, then you should follow the course as taken. What do you believe would be the most reasonable course of action the Department could take to establish a dual rate and correct the audit shortcoming?

Mr. **Kusserow**. At the present time we feel probably moving ahead with the rate as set and then auditing as to how it is functioning, would probably be the best course of action at this time.

Senator **Dole**. Pretty much as the GAO witness indicated?

Mr. **Kusserow**. Yes, sir. I think that at this time that would be the wisest course of action. Our concern was that, originally, we should have looked at the median of the free-standing facilities, along with home dialysis treatment, and the median of hospital-based facilities, along with home dialysis, and develop a composite rate out of that. But at this time I think that we would be better off implementing this regulation, and then auditing, and then making adjustments based upon what we find in our audits.

Senator **Dole**. Now, your office has audited several independent facilities and has come across so-called related organization transactions. Were your findings with respect to those transactions pretty much the same as the GAO reports in that they inflate costs by unallowable or unreasonable amounts?

Mr. **Kusserow**. Yes, sir. They are very consistent with what GAO found.

Senator **Dole**. Could you give me more specifics? What did you find? Give me some examples of where they have inflated the costs. In other words, if the purpose is for more effective administration of programs and more effective treatment, that is one thing. But if it is just a mechanism structured to permit more take from the Federal Government, then we want to try to cut it off.

Mr. **Kusserow**. In the one instance I referred to in my statement, we found that costs were overstated by some $835,000. There were unallowable intercompany profits of $308,000 related to leases and another $181,000 in supplies; also duplicate charges and bad debts. And as was the concern of GAO, our concern is that the only way you can get at those figures is to actually look at the related organizations and have an examination of their books, along with that of the facility.

Senator **Dole**. Now, do you have that authority?

Mr. **Kusserow**. Yes, sir.

Senator **Dole**. You intend to do that?

Mr. **Kusserow**. Yes, sir.

Senator **Dole**. Is it in the process now?

Mr. **Kusserow**. Yes, sir. Our plan is that with the implementation of the new incentive rate, we are going to go behind it and do a statistical sample of audits to see how the program is actually functioning, and in those instances where you have related organizations, then the audit will encompass that relationship.

Senator **Dole**. And how long do you think that might take?

Mr. **Kusserow**. We are planning to have audits over the next 2 years in this area that should provide, each year, statistically valid information to assist HCFA in adjusting rates.

Senator **Dole**. What is the penalty, if any, for anyone in this area who overstates costs when it is obvious that the organizational structure is only there to pick up more money under the program rather than to provide service?

Mr. **Kusserow**. There are two parts to that, Mr. Chairman. One would be that under the system that is currently in force that you could disallow that portion which was improper.

Senator **Dole**. And I think HCFA did that in some areas, I think, 15 percent.

Mr. **Kusserow**. Yes, sir.

Senator **Dole**. I might add while I am on that, did that in any way impact upon patient care?

Mr. **Kusserow**. No, sir. We found no indications that it would impact on that at all. The second part of your question, Mr. Chairman, is that if we found that the impropriety went to a criminal culpability, there is conceivable criminal prosecutions that could arise, if there is falsified data or something of that sort.

Senator **Dole**. All right. But just being too generous would not fall in that category?

Mr. **Kusserow**. No, sir. But under the proposed incentive rate that is being considered by the Department, it really wouldn't matter because there would be an absolute limit. And so whatever they would claim would be irrelevant. And then as far as we are concerned we could then examine the books and records and determine whether that limit was proper or not.

Senator **Dole**. As I understand your statement, apparently most patients, they see their nephrologist, and he says you ought to have dialysis in this clinic or that clinic or in the hospital. Has your work led to any conclusion? Is that just the normal reaction from physicians?

Mr. **Kusserow**. Mr. Chairman, during the first half of 1980 we performed a service delivery assessment of the end stage renal disease program which involved 14 facilities in 10 States. We spoke with dialysis patients, persons with kidney transplant, medical staff, ESRD network staff, and others. This assessment focused on nonhospital dialysis facilities in an urban area. This type of facility now serves about 50 percent of all the dialysis patients and is on the increase. And we reported our findings to the Secretary in September 1980. We did find one that, largely because of the influence of a nephrologist, the kidney specialist, most patients were dialyzed at a facility of his selection and seldom switched to home dialysis or undergo kidney transplant unless recommended by the nephrologist. Second, patients exercised little choice among available dialysis facilities.

Senator **Dole**. But why do they do that? I know what you found. But did you reach any conclusion on why? They just have that much faith in their physician? Is that it?

Mr. **Kusserow**. In most cases, the patients suffered a great deal as a result of having a loss of kidney function, and immediately turned to their physician for guidance. In almost every case, it was a very traumatic experience and under those circumstances they relied heavily upon what the physician would guide them to do.

Senator Dole. But was there any relationship between the physician and the clinic? I mean, was there any business tie between the two?

Mr. Kusserow. The service delivery assessment itself did not look at that side. It only examined the delivery of the actual program benefits. The audits looked at the financial overtones.

Senator Dole. Finally, is there any reason for a patient to shop around for service? There is no benefit to the patient, is there?

Mr. Kusserow. No, sir, not at all.

Senator Dole. So it doesn't make any difference what the cost is.

Mr. Kusserow. Yes. We effectively, through the ESRD program, have become the sole purchaser of that particular program benefit, and, therefore, there really is no competition.

Senator Dole. Senator Baucus?

Senator Baucus. Mr. Kusserow, I want to thank you for being forthright in taking a slightly different view than HCFA. I appreciate very much your candor, your objectivity and your independence. It makes a big difference to us. In your view, is there to some degree, some "cream-skimming" by freestanding facilities? That is, do they do better financially because they are able to get less expensive patients?

Mr. Kusserow. Senator, the data is very sparse here, but what evidence there is seems to suggest that the sicker patients tend to be associated more with the hospital-based facilities than with the freestanding facilities. If that were true, it would place a greater burden on hospitals than on freestanding facilities, thereby resulting in a differential in costs.

Senator Baucus. So you don't agree with the $4 differential between the hospitals and freestanding that is being proposed?

Mr. Kusserow. We feel that it is more expensive to provide dialysis treatment at hospitals than it would be at a freestanding facility.

Senator Baucus. Thank you very much. I have no further questions, Mr. Chairman.

Senator Dole. Well, thank you very much. And we will be working with you in this area because, again without trying to prejudge, I think it is a very expensive program. And again as we are looking around trying to find a dollar here and a dollar there to reduce the deficits, to bring down interest rates, and to ease the burden on the American taxpayer, I think we have a responsibility not only to provide good quality care for the patient but to make certain that we are not paying more than the taxpayer should. And it would appear to me, based on not only this hearing but other information, that except for patients this program is pretty rich for those who are on the receiving end. And we hope you are going to continue to press as quickly as you can to get additional information because we need it. And as soon as you have it, we would like to be informed of it without another hearing. In other words, keep in touch with us.

Mr. Kusserow. Yes, sir, Mr. Chairman. Whatever the rate is, as soon as it is implemented we will immediately implement the audit plan that we have developed and report to you on each item as we find it.

Senator DOLE. Thank you very much. There may be additional questions from other members of the subcommittee.

Our next witness is Carolyne Davis, Dr. Davis, Administrator, Health Care Financing Administration, Department of HHS. Dr. Davis, you may proceed in any way you wish. Your entire statement will be made a part of the record. You can summarize. Do you have charts?

Dr. DAVIS. Yes, I do.

Senator DOLE. And we would be happy to hear from you. And I assume there are copies of the charts.

Dr. DAVIS. There are copies, yes.

Senator DOLE. They will also be made part of the record.

[The prepared statement and charts follow:]

STATEMENT OF
CAROLYNE K. DAVIS, PH.D.
ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

SUMMARY

- PROPOSED REIMBURSEMENT SYSTEM WILL BENEFIT ALL ESRD PROGRAM PARTIES.
  - FEDERAL GOVERNMENT WILL BENEFIT THROUGH LOWER EXPENDITURES.
  - FACILITIES WILL BENEFIT THROUGH POTENTIAL FOR ADDITIONAL PROFITS.
  - PATIENTS WILL BENEFIT BY MORE OPPORTUNITIES FOR HOME DIALYSIS.
- THE CURRENT SYSTEM OF MEDICARE REIMBURSEMENT RULES IS PARTLY TO BLAME FOR THE DRAMATIC INCREASE IN ESRD PROGRAM EXPENDITURES.
- THE PROPOSED REGULATION — WHICH PROVIDES FOR PROSPECTIVE COMPOSITE RATES APPLICABLE TO BOTH IN-FACILITY AND HOME DIALYSIS —
  - DIFFERENTIATES BETWEEN HOSPITAL-BASED AND FREE-STANDING FACILITIES,
  - PROVIDES GREATER INCENTIVES FOR HOME DIALYSIS,
  - INCLUDES AREA WAGE ADJUSTMENT, AND
  - PROVIDES FOR AN EXCEPTIONS PROCESS.
- THE COST DATA USED TO DETERMINE PROPOSED INCENTIVE REIMBURSEMENT RATES WERE BASED ON TWO SETS OF AUDITS OF REPRESENTATIVE SAMPLES OF FACILITIES TO IDENTIFY COSTS OF IN-FACILITY DIALYSIS AND OF HOME DIALYSIS.
- PROPOSED REGULATION ALSO ELIMINATES DISINCENTIVE FOR PHYSICIANS TO TREAT HOME DIALYSIS PATIENTS BY EQUALIZING PHYSICIAN REIMBURSEMENT FOR IN-FACILITY AND HOME DIALYSIS PATIENTS.
- PROPOSED SYSTEM SIMPLIFIES ESRD CLAIMS PROCESSING ACTIVITIES OF INTERMEDIARIES AND CARRIERS.

Mr. Chairman, I am Carolyne K. Davis, the Administrator of the Health Care Financing Administration (HCFA). Accompanying me today are Robert Streimer of the Bureau of Program Policy and Martin Kappert, Deputy Associate Administrator for Operations. We are pleased to be here with you to continue our discussion of the administration of the Medicare End Stage Renal Disease (ESRD) program. In your first hearing last September, we reviewed the operation and management of the program. This morning, as you requested, we will review the background and methodology of the new proposed regulation governing reimbursement of ESRD facilities and physicians. This proposed regulation would establish an efficient and cost effective reimbursement system for ESRD services and one which maintains our commitment to the health and welfare of ESRD patients.

The current system of Medicare reimbursement rules is partly to blame for the dramatic increase in ESRD program expenditures. As I outlined to you last September, if there were no changes in current reimbursement rules, we estimate that total costs for the ESRD program may rise to as much as $1.8 billion in FY 1982 and to almost $2.4 billion by 1984. The Congress and the Administration have both recognized that changes must be made to restrain such cost increases. The 1981 Omnibus Reconciliation Act's ESRD incentive Reimbursement provision and its implementing regulation that we are discussing today, represent a major step in achieving this

GOAL. BEFORE DISCUSSING THIS REGULATION IN DETAIL, I WOULD LIKE TO QUICKLY REVIEW THE CHARACTERISTICS OF ESRD PROVIDERS AND OUR CURRENT REIMBURSEMENT SYSTEM.

INDUSTRY COMPOSITION

KIDNEY DIALYSIS TREATMENTS ARE MOST FREQUENTLY PROVIDED IN ONE OF TWO SETTINGS: HOSPITAL-BASED FACILITIES OR FREE-STANDING FACILITIES. THE NUMBER OF HOSPITAL-BASED FACILITIES HAS REMAINED RELATIVELY STABLE SINCE THE INCEPTION OF THE PROGRAM. THERE WERE 536 HOSPITAL-BASED FACILITIES IN 1973 COMPARED TO 654 IN 1981. FREE-STANDING FACILITIES, HOWEVER, HAVE EXPERIENCED A DRAMATIC GROWTH DURING THE SAME TIME PERIOD. THERE WERE 68 SUCH FACILITIES IN 1973 COMPARED TO 466 IN 1981.

THERE ARE MAJOR DIFFERENCES IN THE NATURE, ORGANIZATIONAL STRUCTURE AND LOCATION OF HOSPITAL-BASED FACILITIES AND FREE-STANDING PROVIDERS.

- OVER 75 PERCENT OF ALL FREE-STANDING FACILITIES ARE PRIVATE, FOR-PROFIT ENTITIES, WHILE ONLY 5 PERCENT OF HOSPITALS FURNISHING OUTPATIENT DIALYSIS FALL INTO THIS CATEGORY.
- OVER 50 PERCENT OF ALL FREE-STANDING FACILITIES ARE LOCATED IN SEVEN STATES (CALIFORNIA, FLORIDA, GEORGIA, NEW YORK, PENNSYLVANIA, TEXAS AND ILLINOIS). EIGHT STATES, MOSTLY WITH LESS URBANIZED AREAS, HAVE NO INDEPENDENT FACILITIES. HOSPITAL-BASED FACILITIES, ON THE OTHER HAND, ARE MORE EVENLY DISPERSED THROUGHOUT THE COUNTRY.

- OVER HALF OF THE FREE-STANDING FACILITIES ARE MEMBERS OF CHAIN ORGANIZATIONS, THE LARGEST OF WHICH OWNS OR OPERATES APPROXIMATELY ONE-THIRD OF THE TOTAL INDEPENDENT FACILITIES. VERY FEW HOSPITALS ARE MEMBERS OF CHAIN ORGANIZATIONS.

CURRENT MEDICARE REIMBURSEMENT RULES

AS I STATED, CURRENT MEDICARE REIMBURSEMENT RULES HAVE CONTRIBUTED TO THE DRAMATIC INCREASE IN ESRD EXPENDITURES. HOSPITALS, ON THE ONE HAND, ARE REIMBURSED FOR THEIR REASONABLE COSTS. THAT IS, MEDICARE GENERALLY PAYS HOSPITALS WHATEVER THEY SPEND FOR DIALYSIS TREATMENT. THIS METHOD OFFERS LITTLE INCENTIVE TO THE FACILITIES TO MAKE THEIR OPERATIONS MORE EFFICIENT SINCE THEY MAY NOT RETAIN ANY EXCESS OF MEDICARE REVENUES OVER MEDICARE COSTS EVEN IF THESE COSTS ARE REDUCED THROUGH MORE EFFICIENT OPERATION. FREE-STANDING FACILITIES, ON THE OTHER HAND, ARE REIMBURSED ON THE BASIS OF THEIR REASONABLE CHARGES, UP TO A MAXIMUM PAYMENT SCREEN OF $138 PER TREATMENT. NEARLY ALL FREE-STANDING FACILITIES CLAIM THIS MAXIMUM REASONABLE CHARGE AND ARE PAID AT THE RATE OF $138 PER TREATMENT. THESE FACILITIES MAY RETAIN THE TOTAL DIFFERENCE BETWEEN THEIR CHARGES AND ACTUAL COSTS.

WITH RESPECT TO IN-FACILITY DIALYSIS, WE HAVE CONDUCTED AUDITS TO DETERMINE HOW OUR REIMBURSEMENT AMOUNTS COMPARED WITH THE ACTUAL COSTS OF PROVIDING DIALYSIS. THESE AUDITS INCLUDED THE COSTS OF DIALYSIS PROVIDED IN BOTH TYPES OF FACILITIES.

Audited ESRD cost data analyzed in 1981 show that the median cost per in-facility dialysis was $135 for hospital-based facilities. This cost was some 25 percent higher than the $108 median for free-standing facilities. We believe that this disparity in costs between the two types of facilities reflects the absence that I mentioned of effective incentives for maximum efficiency in the cost-based hospital setting. Of equal concern to the Department, however, is the fact that despite the median costs of $108 per treatment, nearly all free-standing facilities have charged $138 per treatment. Hence, neither the Federal Government nor the ESRD beneficiary population had benefited fully from the operating efficiencies and lower costs of the free-standing facilities.

With respect to home dialysis, additional audit data show median costs to be about $97 per treatment. Although home dialysis is believed to be suitable and appropriate for as many as 30 to 40 percent of all ESRD patients, it is actually used for only about 17 percent of patients nationwide. Within this national average there are wide variations among geographical areas. For example, the rate for California is only 9.1 percent while the rate for Washington State is 54.2 percent. Hence, the potential benefits to be gained from wider use of this lower-cost treatment modality have also not accrued to the ESRD program. In addition to the financial advantages, home dialysis patients can lead a more normal life with increased opportunities for independence, rehabilitation, and meaningful employment.

AUDITS

THESE DATA WERE DERIVED FROM AUDITS OF TWO SAMPLES OF FACILITIES. SINCE QUESTIONS HAVE BEEN RAISED ABOUT THE OBJECTIVITY OF THESE AUDITS, I WOULD LIKE TO TAKE A FEW MINUTES TO DESCRIBE HOW THEY WERE CONDUCTED. IN ORDER TO SELECT A REPRESENTATIVE SAMPLE OF FACILITIES TO AUDIT, WE DIVIDED ALL OF THE OPERATING FACILITIES INTO FOUR GROUPS (URBAN HOSPITAL, URBAN INDEPENDENT, RURAL HOSPITAL AND RURAL INDEPENDENT) AND THEN STRATIFIED THESE GROUPS BY TOTAL REPORTED COSTS. FROM THIS ARRAY, WE SELECTED FACILITIES FROM EACH STRATUM (E.G., URBAN INDEPENDENT FACILITIES WITH REPORTED ANNUAL COSTS OF $500,000 OR LESS). THIS STATISTICAL SAMPLING PROCESS LED TO THE SELECTION IN MARCH 1980 OF A STRATIFIED SAMPLE OF 110 FACILITIES FROM 825 NON-FEDERAL ESRD FACILITIES THAT WERE FURNISHING IN-FACILITY OUTPATIENT DIALYSIS SERVICES AT THAT TIME. THIS INITIAL SAMPLE INCLUDED 70 OF THE HOSPITAL-BASED FACILITIES AND 40 OF THE FREE-STANDING FACILITIES, WHICH AMOUNTED TO 13 PERCENT OF ALL FACILITIES THAT WERE OPERATING.

THE AUDITS ACTUALLY PERFORMED INVOLVED 38 FREE-STANDING FACILITIES AND 67 HOSPITALS. AS I MENTIONED, THESE AUDITS WERE CONDUCTED SO THAT WE COULD ESTIMATE THE ACTUAL COSTS OF PROVIDING IN-FACILITY DIALYSIS SERVICES IN ACCORDANCE WITH MEDICARE COST-REPORTING PRINCIPLES. THESE COST ESTIMATES WERE TO BE USED FOR THE PURPOSE OF ESTABLISHING AN INCENTIVE REIMBURSEMENT METHODOLOGY AND PAYMENT RATES FOR FACILITY

DIALYSIS, AS MANDATED BY THE END-STAGE RENAL DISEASE AMENDMENTS OF 1978.

RECONCILIATION ACT OF 1981

BEFORE THE DEPARTMENT COULD IMPLEMENT SUCH AN INCENTIVE REIMBURSEMENT SYSTEM, THE RECONCILIATION ACT OF 1981 WAS ENACTED. AS YOU KNOW, THE 1981 ACT MANDATED THAT PAYMENTS FOR ESRD SERVICES DIFFERENTIATE BETWEEN HOSPITAL-BASED AND FREE-STANDING TYPES OF FACILITIES AND PROVIDE GREATER INCENTIVES FOR HOME DIALYSIS. THIS WAS TO BE ACHIEVED BY A COMPOSITE RATE THAT WOULD APPLY TO BOTH HOME DIALYSIS AND FACILITY TREATMENTS, OR BY A MORE EFFICIENT ALTERNATIVE.

HOWEVER, BECAUSE THE FIRST GROUP OF AUDITS HAD INCLUDED ONLY THE COSTS OF IN-FACILITY DIALYSIS IT WAS NECESSARY TO CONDUCT A SECOND GROUP OF AUDITS TO IDENTIFY THE COSTS OF HOME DIALYSIS. WITH THE COSTS OF HOME DIALYSIS IDENTIFIED, WE WOULD THEN BE ABLE TO INCLUDE THOSE COSTS IN THE COMPOSITE RATE AS REQUIRED BY THE 1981 ACT. THESE AUDITS WERE CONDUCTED LAST FALL IN COOPERATION WITH THE OFFICE OF THE INSPECTOR GENERAL. THE AUDIT SAMPLE CONSISTED OF 25 OF THE LARGEST HOME DIALYSIS PROGRAMS IN THE COUNTRY, REPRESENTING THE EXPERIENCE OF 30 PERCENT OF ALL HOME DIALYSIS PATIENTS.

I SHOULD NOTE THAT BECAUSE OF THE SEVERE TIME RESTRAINTS IMPOSED BY THE LAW, IT WAS IMPOSSIBLE TO DETERMINE IF ALL OF THE REPORTED COSTS WERE REASONABLE AND ALLOWABLE UNDER THE MEDICARE REIMBURSEMENT PRINCIPLES. HOWEVER, WE BELIEVE THAT OUR AGGREGATE COST REVIEW RESULTS REASONABLY REPRESENT THE

MEDIAN COSTS OF FURNISHING HOME DIALYSIS. WE WILL, OF COURSE, REVIEW ALL REPORTED COSTS ANNUALLY TO DETERMINE WHAT ADJUSTMENTS ARE NEEDED IN THE RATES.

NOW, I WILL DISCUSS FURTHER THE INCENTIVE RATE REIMBURSEMENT SYSTEM PROVIDED FOR UNDER THE 1981 RECONCILIATION ACT. THE STATUTE SPECIFIES A PREFERENCE FOR SEPARATE COMPOSITE RATES -- I.E., ONE COMPOSITE RATE FOR HOSPITALS AND ANOTHER FOR FREE-STANDING FACILITIES. THESE RATES ARE TO TAKE INTO ACCOUNT THE COSTS OF IN-FACILITY AND AT-HOME DIALYSIS AND THE RESPECTIVE PROPORTIONS OF PATIENTS DIALYZING IN EACH LOCATION. THE COMPOSITE RATES WOULD THEN BE PAID FOR EACH TREATMENT, WHETHER RENDERED AT A FACILITY OR AT HOME.

COMPOSITE RATES ARE EXPECTED TO YIELD A SUBSTANTIAL FINANCIAL INCENTIVE TO A FACILITY FOR EACH PATIENT WHO IS DIALYZED AT HOME AND WITH A LOWER PAYMENT RATE FOR THOSE TREATED IN THE FACILITY. SINCE WE WILL BE PAYING THE SAME RATE FOR DIALYSIS PERFORMED IN THE HOME AND DIALYSIS PERFORMED IN A FACILITY -- AND HOME DIALYSIS IS LESS COSTLY ON THE AVERAGE -- ALL PROVIDERS WILL HAVE AN INCENTIVE TO SHIFT PATIENTS TO HOME DIALYSIS WHERE PHYSICIANS DETERMINE THAT HOME DIALYSIS IS SUITABLE. THE PROMOTION OF THIS INCENTIVE IS THE MOST IMPORTANT OBJECTIVE OF THE 1981 LEGISLATIVE PROVISION AND OF OUR REGULATIONS. IF WE CAN ENCOURAGE A SHIFT TO HOME DIALYSIS WHEREBY THE NATIONAL RATE EVEN REMOTELY APPROACHES THAT FOR WASHINGTON STATE (54.2 PERCENT), THE PROGRAM'S RATE OF COST INCREASES CAN BE SUBSTANTIALLY REDUCED.

DESCRIPTION OF METHODOLOGY

THE ACTUAL PAYMENT METHODOLOGY THAT WE EMPLOYED USES AS A DEPARTURE POINT THE MEDIAN COSTS OF HOME DIALYSIS AND OF FACILITY DIALYSIS FOR ALL FACILITIES AUDITED. THESE COSTS WERE THEN WEIGHTED BY THE PROPORTIONS OF PATIENTS DIALYZING IN EACH LOCATION (I.E., OF HOSPITAL PATIENTS, 23.5 PERCENT DIALYZE AT HOME AND 76.5 PERCENT IN FACILITY; OF INDEPENDENT ESRD PATIENTS, 10.5 PER CENT ARE AT HOME AND 89.5 PERCENT ARE IN FACILITY).

THE DEPARTMENT THEN DETERMINED THAT THE RECONCILIATION ACT REQUIREMENT FOR DIFFERENTIATION BETWEEN HOSPITAL AND INDEPENDENT FACILITIES SHOULD FURTHER BE CARRIED OUT BY ADJUSTING THE HOSPITAL RATE TO ACCOUNT ONLY FOR LEGITIMATE HIGHER COSTS INCURRED BY HOSPITALS AS A GROUP. THE HOSPITAL RATE WAS THEREFORE RAISED BY $2.10 TO ACCOUNT FOR AN APPARENT EXCESS (OVER THE MEDIAN FOR ALL FACILITIES) IN HOSPITAL OVERHEAD COSTS RESULTING FROM MEDICARE HOSPITAL ACCOUNTING REQUIREMENTS. NO ADJUSTMENT WAS MADE TO RECOGNIZE THE HOSPITAL'S GENERALLY HIGHER COSTS OF LABOR AND SUPPLIES SINCE WE HAVE NO EVIDENCE THAT SUCH EXCESS COSTS ARE JUSTIFIABLE FOR HOSPITALS AS A CLASS OF PROVIDERS.

ONE FURTHER ADJUSTMENT WAS MADE. A FIVE-PERCENT FACTOR WAS ADDED TO THE HOSPITAL RATE TO ACCOUNT FOR THE POSSIBILITY THAT THE METHODOLOGY USED MAY HAVE FAILED TO RECOGNIZE FULLY THE LEGITIMATE COSTS OF HOSPITALS OR SHORTCOMINGS IN THE AUDITED DATA. A FACTOR OF EQUAL CONCERN WAS THAT THE USE OF COMPOSITE RATES HAS A MORE SEVERE EFFECT ON HOSPITALS THAN

FREE-STANDING FACILITIES. THIS OCCURS BECAUSE THE PERCENTAGE OF HOME DIALYSIS PATIENTS IS PRESENTLY GREATER FOR HOSPITALS THAN FOR FREE-STANDING FACILITIES.

ANOTHER FACTOR USED IN SETTING THE RATE IS THE REQUIREMENT IN THE CONFERENCE COMMITTEE REPORT ON THE 1981 ACT THAT THE RATES PAID TO INDIVIDUAL FACILITIES WOULD VARY WITH LOCAL LABOR COSTS. WE FOUND THAT THE MOST RELIABLE WAGE DATA AVAILABLE TO BE THAT COMPILED BY THE BUREAU OF LABOR STANDARDS (BLS) AND USED FOR THE MEDICARE HOSPITAL COSTS LIMITS. FROM THE BLS DATA WE DEVELOPED AREA WAGE INDEXES THAT REFLECT THE RELATION OF LOCAL WAGE LEVELS TO THE NATIONAL AVERAGE.

FINALLY, AFTER TAKING ALL OF THESE FACTORS INTO ACCOUNT, THE COMPUTATION OF THE INCENTIVE REIMBURSEMENT RATE YIELDS AN AVERAGE PAYMENT PER TREATMENT OF $132 FOR HOSPITAL-BASED FACILITIES (RANGING FROM A LOW OF $114 TO A HIGH OF $148). THE AVERAGE RATE FOR INDEPENDENT FACILITIES WOULD BE $128 (RANGING FROM A LOW OF $109 TO A HIGH OF $143). AS I STATED EARLIER, THE SAME RATE WOULD BE PAID FOR BOTH HOME AND IN-FACILITY DIALYSIS. MOREOVER, IT IS A PROSPECTIVE RATE, AND UNLIKE THE PROCESS OF THE PRESENT COST-REIMBURSEMENT METHOD, THERE WOULD BE NO COST SETTLEMENT AT THE END OF THE PERIOD.

EXCEPTIONS

THE PROPOSED REGULATION ALSO PROVIDES FOR AN EXCEPTIONS PROCESS THAT WOULD ALLOW THE PAYMENT OF HIGHER RATES FOR

FACILITIES WITH JUSTIFIABLY HIGHER COSTS. WE PROPOSE TO CONSIDER EXCEPTIONS TO A FACILITY THAT IS ABLE TO PROVIDE CONVINCING EVIDENCE THAT IT HAS EXCESSIVE COSTS THAT ARE ATTRIBUTABLE TO ONE OF THE FOLLOWING CONDITIONS:

o ATYPICAL PATIENT MIX; FOR EXAMPLE, A PEDIATRIC DIALYSIS UNIT HAS UNUSUAL REQUIREMENTS;

o. ISOLATED ESSENTIAL FACILITIES;

o EXTRAORDINARY CIRCUMSTANCES (FLOODS, FIRES, ETC.); AND

o EDUCATIONAL COSTS: IF COSTS ARE DIRECTLY ATTRIBUTABLE TO APPROVED EDUCATION PROGRAMS THAT INVOLVE OUTPATIENT DIALYSIS SERVICES.

ANY FACILITY WHOSE EXCEPTION REQUEST IS DENIED COULD APPEAL TO THE INTERMEDIARY , AND, SUBSEQUENTLY, IF THE AMOUNT IN DISPUTE IS $10,000 OR MORE, TO THE PROVIDER REIMBURSEMENT REVIEW BOARD ESTABLISHED UNDER THE MEDICARE LAW. THE LAW ALSO PROVIDES FURTHER RIGHT OF APPEAL TO THE U.S. DISTRICT COURT.

PHYSICIAN REIMBURSEMENT

WE ARE ALSO PROPOSING TO REVISE PHYSICIAN REIMBURSEMENT METHODS TO PROMOTE EFFICIENT DELIVERY OF DIALYSIS SERVICES AND PROVIDE INCENTIVES FOR HOME DIALYSIS. CURRENTLY, THERE ARE TWO WAYS THAT PHYSICIANS ARE PAID FOR THEIR ESRD SERVICES -- THE INITIAL METHOD (IM) AND THE ALTERNATIVE REIMBURSEMENT METHOD (ARM). UNDER THE INITIAL METHOD, REIMBURSEMENT FOR SUPERVISORY PATIENT CARE SERVICES IS MADE TO A

FACILITY AS PART OF THE FACILITY'S REIMBURSEMENT RATE.

NON-SUPERVISORY SERVICES ARE PAID ON AN INDIVIDUAL FEE-FOR-SERVICE BASIS. ALL SERVICES FURNISHED TO HOME DIALYSIS PATIENTS ARE BILLED ON AN INDIVIDUAL FEE-FOR-SERVICE BASIS. THE PHYSICIAN MUST PHYSICALLY SEE THE PATIENT IN ORDER TO BE PAID, SINCE NO ALLOWANCE IS MADE FOR GENERAL SUPERVISION.

UNDER THE ALTERNATIVE REIMBURSEMENT METHOD, PHYSICIANS ARE PAID A COMPREHENSIVE MONTHLY FEE (APPROXIMATELY $220 PER PATIENT PER MONTH) FOR ALMOST ALL OF THE ESRD SERVICES FURNISHED TO PATIENTS DIALYZED IN FACILITIES. BECAUSE THERE IS ONE MONTHLY BILL, THERE IS MORE CONTROL OVER THE OVERALL REIMBURSEMENT PHYSICIANS RECEIVE. PHYSICIANS ARE ALSO PAID ON THE BASIS OF A LOWER MONTHLY FEE FOR SUPERVISING ALL OF THEIR HOME DIALYSIS PATIENTS. ON THE AVERAGE, THIS FEE IS $154 PER PATIENT PER MONTH.

THE CURRENT REIMBURSEMENT METHODS PROVIDE AN ECONOMIC INCENTIVE FOR PHYSICIANS TO TREAT DIALYSIS PATIENTS IN A FACILITY, RATHER THAN AT HOME. THIS IS, OF COURSE, INCONSISTENT WITH THE STATUTORY GOAL TO STIMULATE HOME DIALYSIS. I BELIEVE THAT WE MUST DEAL WITH PHYSICIAN INCENTIVES AS WELL AS FACILITY INCENTIVES BECAUSE THE PHYSICIAN IS THE PRIMARY DECISION-MAKER ON HOW TREATMENT IS TO BE FURNISHED.

WE HAVE PROPOSED TO DO THIS BY ELIMINATING THE INITIAL METHOD AND ESTABLISHING EQUAL PHYSICIAN CAPITATION MONTHLY

PAYMENTS FOR HOME DIALYSIS AND IN-FACILITY DIALYSIS. THIS WILL MEAN TOTAL FEDERAL NEUTRALITY AS TO WHERE PATIENTS ARE PLACED AND THE SPECIFIC MODE OF TREATMENT PRESCRIBED. IN THIS WAY, WE WOULD NOT, AS UNDER CURRENT PRACTICES, GIVE PHYSICIANS A FINANCIAL INCENTIVE FOR TREATING THEIR PATIENTS IN THE FACILITY RATHER THAN AT HOME BY PAYING THEM MORE FOR IN-FACILITY TREATMENT. WE ARE PROPOSING IN THE NEW REGULATION AN AVERAGE PAYMENT OF $184 PER MONTH FOR BOTH HOME AND IN-FACILITY PATIENTS. THIS PAYMENT IS BASED ON A COMPOSITE WEIGHTED FORMULA TO ACCOUNT FOR THE PROPORTION OF PATIENTS CURRENTLY DIALYZING AT HOME.

ESRD INTERMEDIARY AUDITING AND INTERMEDIARY/CARRIER CLAIMS PROCESSING ACTIVITIES

THE NEW REIMBURSEMENT SYSTEM WILL ALSO HAVE SOME POSITIVE EFFECTS FOR MEDICARE INTERMEDIARIES AND CARRIERS. AS YOU KNOW, THE FEDERAL GOVERNMENT CONTRACTS WITH THESE ORGANIZATIONS FOR REVIEW AND PAYMENT OF MEDICARE CLAIMS, THE PERFORMANCE OF AUDITS, AND OTHER SUPPORT SRVICES. THESE ORGANIZATIONS ARE ALSO RESPONSIBLE FOR THE REVIEW OF REQUESTS FOR EXCEPTIONS TO THE ESRD REIMBURSEMENT RATES. HCFA MAKES THE FINAL DECISIONS ON EXCEPTION REQUESTS.

THE PROPOSED REIMBURSEMENT SYSTEM REPRESENTS A SIMPLIFICATION OF THE CURRENT SYSTEMS OF COST-BASED PAYMENT FOR HOSPITALS AND CHARGE-BASED PAYMENT FOR FREE-STANDING FACILITIES, AND OF TWO PHYSICIAN PAYMENT SYSTEMS. ACCORDINGLY, WE BELIEVE THE WORKLOAD FOR CARRIERS AND INTERMEDIARIES WILL BE LIGHTER. THEY WILL BE ABLE TO DEVOTE MORE RESOURCES

TO AUDITS AND EXCEPTIONS, AND LESS TO ROUTINE CLAIMS PROCESSING. THEIR OVERALL PERFORMANCE IN THESE AREAS SHOULD BE IMPROVED.

UNDER THE NEW SYSTEM, INTERMEDARIES WILL CONTINUE TO REVIEW EXCEPTION REQUESTS AND AUDIT THESE REQUESTS ON AN AS-NEEDED BASIS. WHEN AN EXCEPTION REQUEST IS RECEIVED, THE SERVING INTERMEDIARY WILL PERFORM A DETAILED REVIEW. SHOULD THIS REVIEW INDICATE THAT THE EXCEPTION REQUEST NEEDS FURTHER DEVELOPMENT, THE INTERMEDIARY WILL SCHEDULE A FULL AUDIT SUBJECT TO APPROVAL BY HCFA. AFTER THE INTERMEDIARY HAS COMPLETED ITS REVIEW, HCFA STAFF WILL MAKE THE DECISION ON GRANTING THE EXCEPTION.

CONCLUSION

IN CONCLUSION, WE BELIEVE THAT THE NEW REIMBURSEMENT SYSTEM MEETS THE STATUTORY REQUIREMENTS THAT ESRD PAYMENT RATES BE PROSPECTIVELY DETERMINED AND COMPOSITE IN NATURE, AND PROVIDE INCENTIVES FOR GREATER USE OF HOME DIALYSIS. THE METHODOLOGY IS EQUITABLE IN CONSIDERING THE COSTS OF ALL FACILITIES. IT REWARDS EFFICIENCY BY ENCOURAGING GREATER USE OF LOWER-COST HOME DIALYSIS AND PERMITTING FACILITIES TO RETAIN THE DIFFERENCE BETWEEN THEIR COSTS AND THEIR PAYMENT RATES, AND IT PROVIDES EXCEPTION FOR FACILITIES THAT CAN DEMONSTRATE UNUSUAL CIRCUMSTANCES. IT WILL BE OF BENEFIT TO ALL PARTIES CONCERNED.

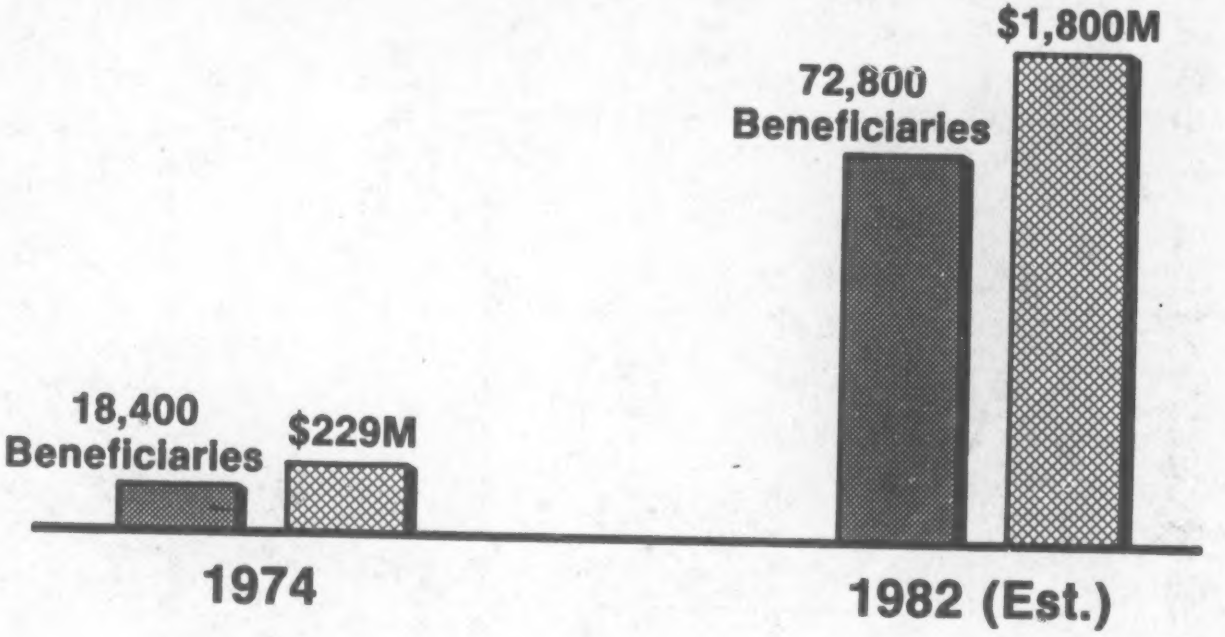
- THE FEDERAL GOVERNMENT WILL BENEFIT THROUGH LOWER EXPENDITURES:

- FACILITIES WILL BENEFIT THROUGH THE POTENTIAL FOR ADDITIONAL PROFITS THAT WILL RESULT FROM MORE EFFICIENT OPERATIONS AND INCREASED USE OF HOME DIALYSIS; AND
- PATIENTS WILL BENEFIT BY HAVING MORE OPPORTUNITIES FOR DIALYSIS AT HOME WHEN THEIR PHYSICIANS DETERMINE THAT HOME DIALYSIS IS APPROPRIATE.

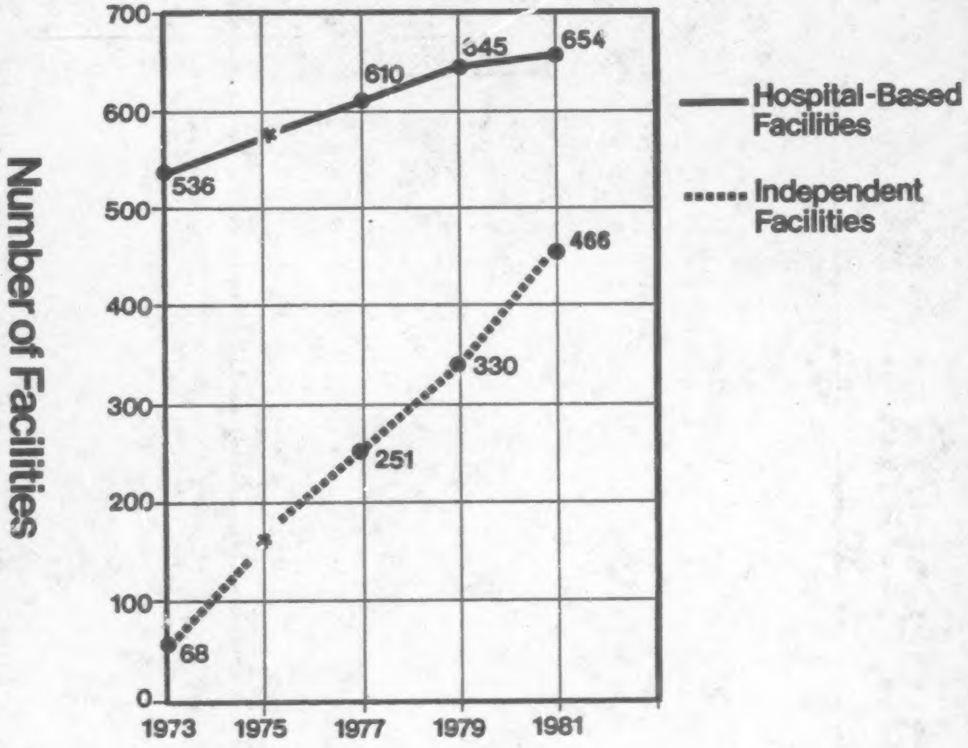
IN CLOSING, I WOULD LIKE TO REITERATE MY PERSONAL CONCERN THAT THE PEOPLE WHO ARE SERVED BY THIS PROGRAM REMAIN OUR HIGHEST PRIORITY. I AM COMMITTED TO A COST-EFFECTIVE SYSTEM WHICH PROVIDES HIGH QUALITY CARE FOR THESE PATIENTS, AND I BELIEVE THIS REGULATION WILL RESULT IN SUCH A SYSTEM.

MR. CHAIRMAN, THIS CONCLUDES MY PREPARED TESTIMONY. I WOULD BE HAPPY TO ANSWER ANY QUESTIONS THAT YOU MAY HAVE.

ESRD PROGRAM GROWTH

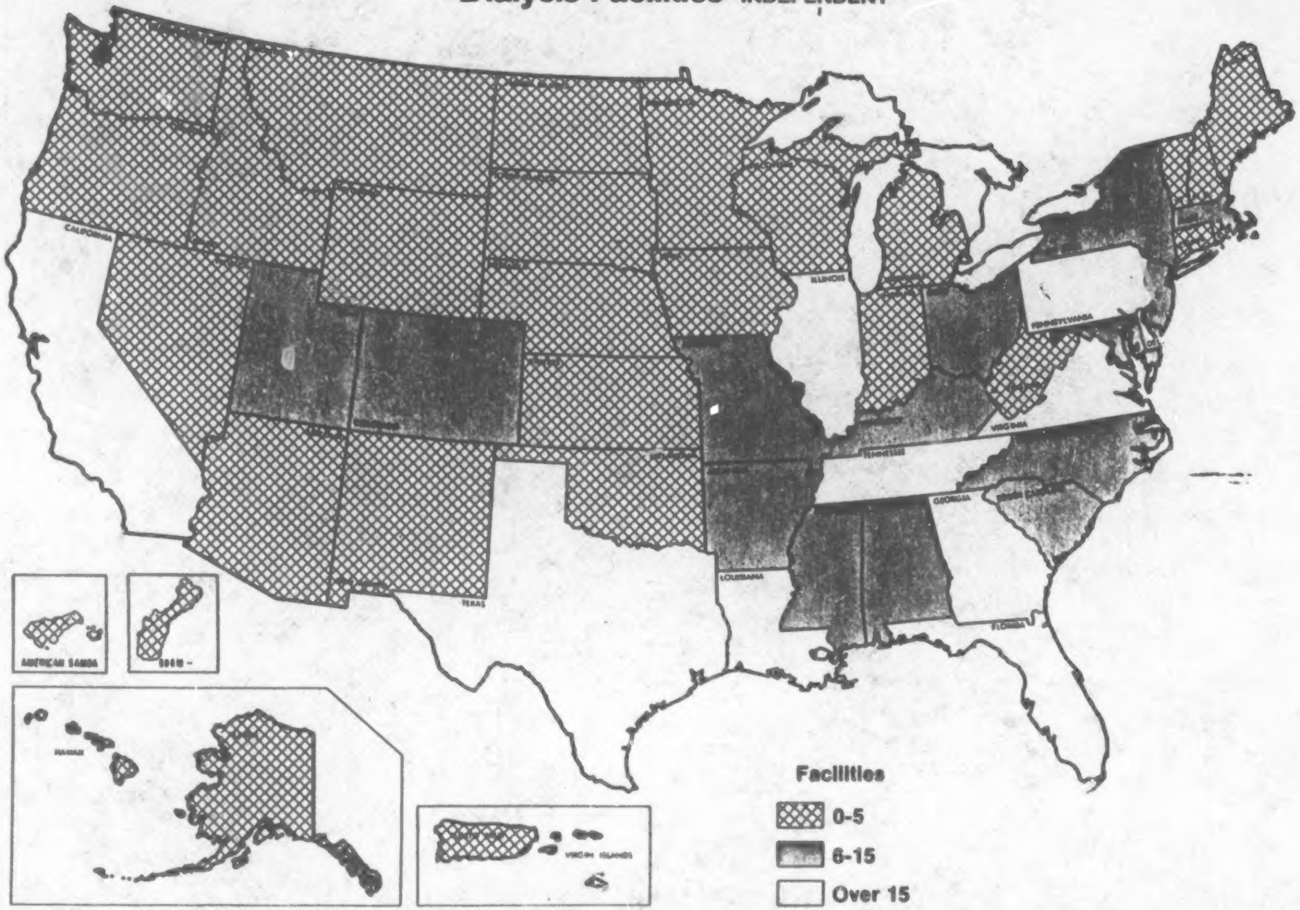


Number of Certified ESRD Facilities

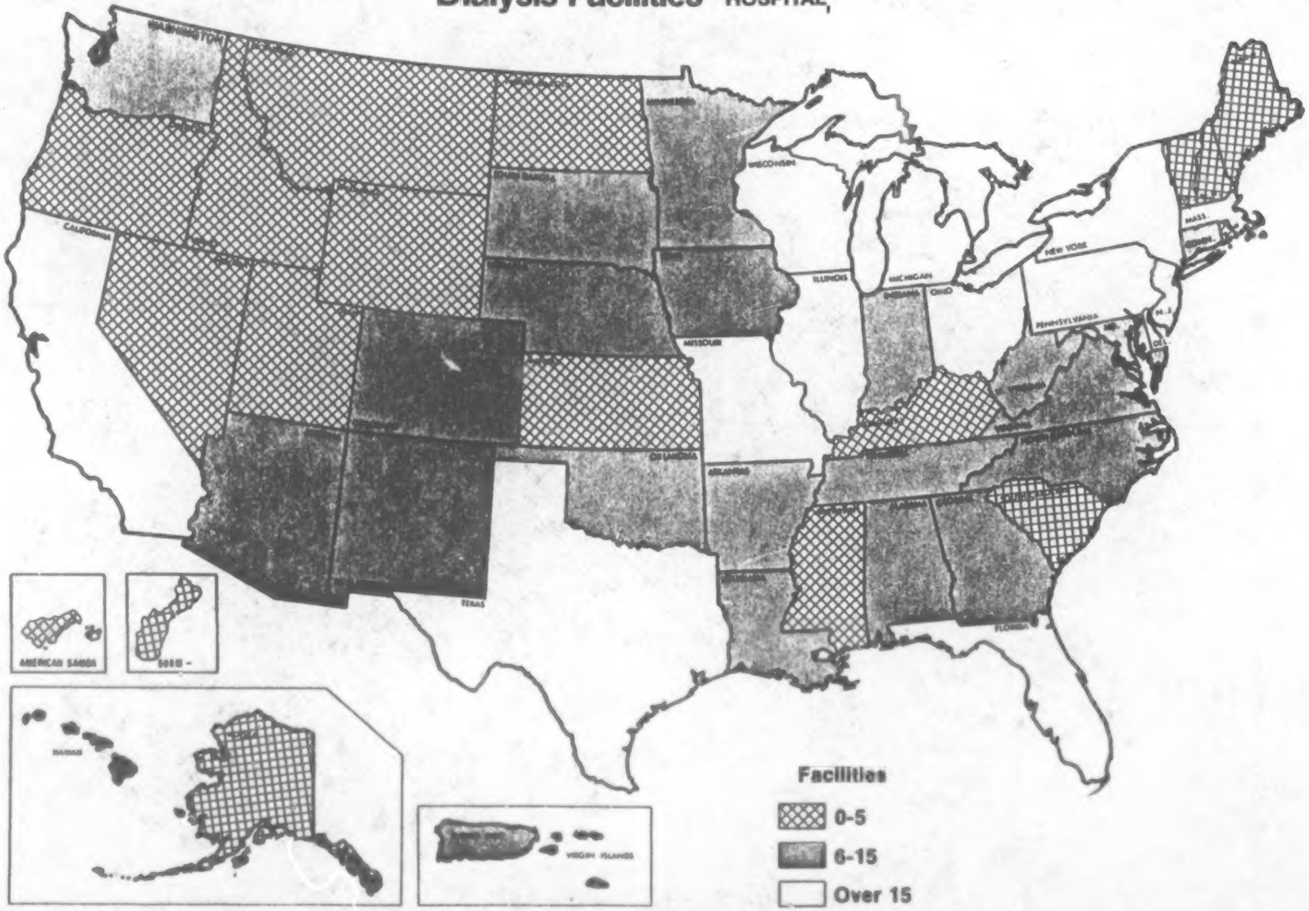


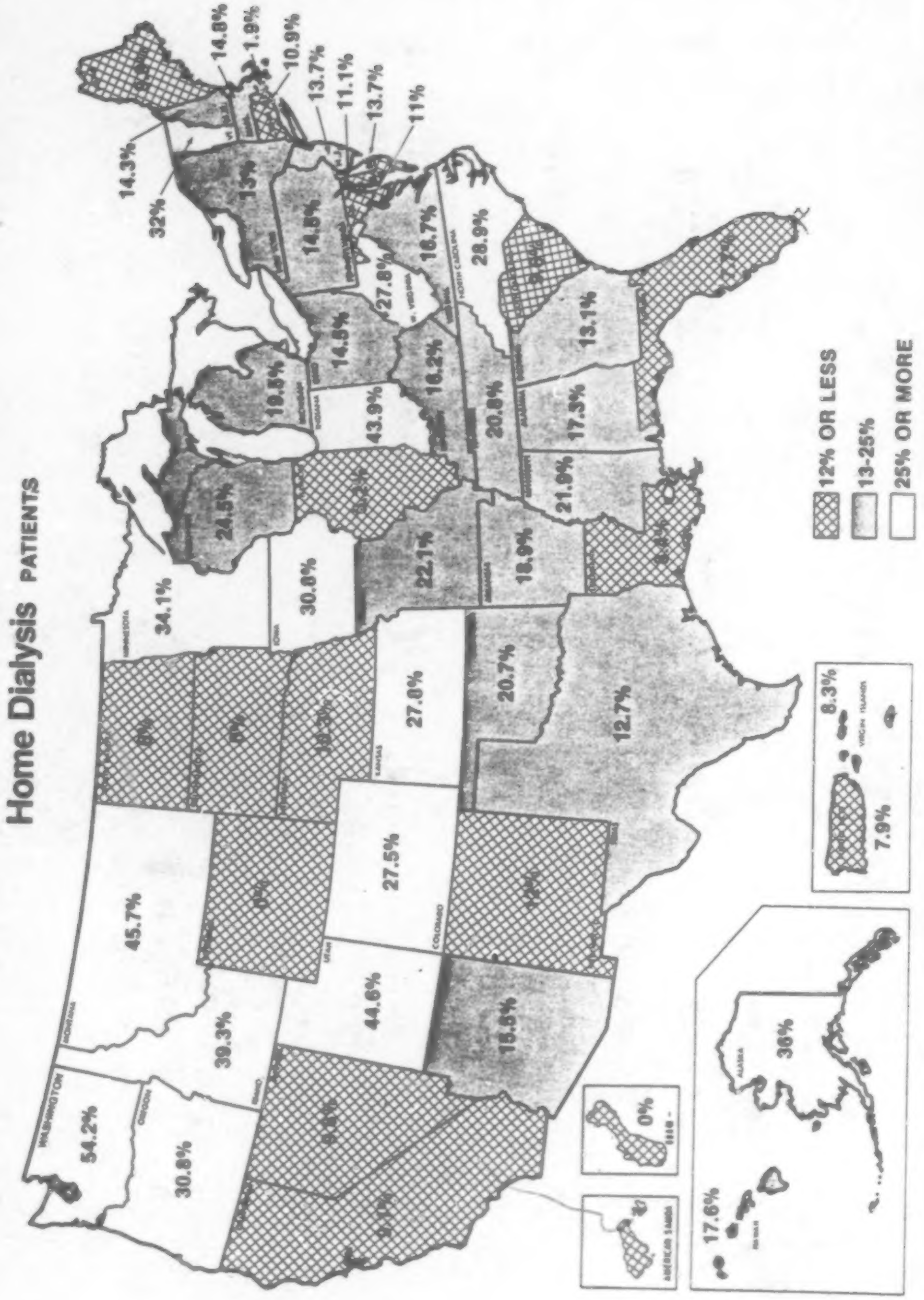
*Data Not Available

Dialysis Facilities INDEPENDENT


CALIFORNIA
TEXAS
ILLINOIS
PENNSYLVANIA
VIRGINIA
TENNESSEE
GEORGIA
LOUISIANA
FLORIDA
AMERICAN SAMOA
HAWAII
VIRGIN ISLANDS
Facilities
0-5
6-15
Over 15

Dialysis Facilities HOSPITAL,


WASHINGTON
CALIFORNIA
SOUTH DAKOTA
MINNESOTA
WISCONSIN
ILLINOIS
MICHIGAN
INDIANA
OHIO
NEW YORK
PENNSYLVANIA
N.J.
DEL.
MASS.
CONN.
MISSOURI
OKLAHOMA
ARKANSAS
TEXAS
FLORIDA
AMERICAN SAMOA
HAWAII
VIRGIN ISLANDS
Facilities
0-5
6-15
Over 15



Home Dialysis PATIENTS

WASHINGTON
54.2%
OREGON
30.8%
9.1%
9.8%
IDAHO
39.3%
MONTANA
45.7%
0%
UTAH
44.6%
COLORADO
27.5%
15.8%
10%
0%
0%
10.3%
KANSAS
27.8%
20.7%
12.7%
MINNESOTA
34.1%
IOWA
30.8%
22.1%
ARKANSAS
18.9%
24.5%
MICHIGAN
19.8%
INDIANA
43.9%
OHIO
14.8%
18.2%
20.8%
21.9%
ALABAMA
17.3%
13.1%
NORTH CAROLINA
28.9%
16.7%
W. VIRGINIA
27.8%
14.8%
NEW YORK
15%
14.3%
32%
14.8%
1.9%
10.9%
13.7%
11.1%
13.7%
11%
ALASKA
36%
HAWAII
17.6%
AMERICAN SAMOA
0%
GUAM
7.9%
8.3%
VIRGIN ISLANDS
▨ 12% OR LESS
▒ 13-25%
☐ 25% OR MORE

RATE CALCULATION

Audit Findings

Median Hospital In-facility Costs	$135	$126
Median Independent In-facility Costs	108	
Median At-home Costs	97	

Hospital Rate

76.5% In-facility 23.5% At-home	⇨	$132 Average Composite Rate (Range: $146-114 after Wage Index Adjustment)

Independent Rate

89.5% In-facility 10.5% At-home	⇨	$128 Average Composite Rate (Range: $143-109 after Wage Index Adjustment)

STATEMENT OF DR. CAROLYNE K. DAVIS, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. DAVIS. Let me introduce the people that are with me. To my left is Mr. Robert Streimer, who is the Acting Director of the Office of Coverage Policy, Bureau of Program Policy, and to my right is Mr. Martin Kappert, who is the Deputy Associate Administrator for Operations. As you have indicated, I do have a complete statement and I will submit that for the record. Let me just highlight a few of the main points.

The proposed regulation, we believe, will establish both an efficient and cost effective ESRD reimbursement system and will maintain our commitment to the patients' health and welfare.

Chart 1 indicates the current medicare reimbursement methods that we think are partly to blame for the increase in ESRD expenditures. If these reimbursement methods are not changed, the cost, which in 1974, was only $229 million, would rise to $1.8 billion in 1982.

Senator DOLE. Do we have what the cost would be in 1974 dollars?

Dr. DAVIS. In 1974 dollars?

Senator DOLE. Yes.

Dr. DAVIS. We would have to submit that for the record for you.

Senator DOLE. A lot of it is probably inflation, plus there are almost four times as many beneficiaries.

Dr. DAVIS. Yes. We will submit that for the record.

[The information follows:]

The value of $1.8 billion in 1982 is approximately equivalent to $1.2 billion of expenditures in 1974 program dollars. This $1.2 billion value takes into account the change in population and mix of services that have occurred from 1974 to 1982.

Dr. DAVIS. We believe that the 1981 Omnibus Budget Reconciliation Act's incentive reimbursement provision and our implementation of the regulations will help to restrain the cost increase. Before I discuss the regulations in detail, I would like to review just for a moment the industry's composition. As you know, dialysis is provided in both the hospital-based and the freestanding facilities. Chart 2 indicates the growth in these program areas. The number of hospital-based facilities, which is the solid line at the top, has remained relatively stable. There were 536 in 1973 and 657 in 1981. However, the growth in the freestanding facilties has been rather dramatic. There were 68 in 1973 and 486 in 1981. There are also several major differences in the ownership and the location of the two types of facilities.

Chart 3 shows the locations of the independent facilities. Over 75 percent of the freestanding facilities are private, for profit organizations. You will notice that there are eight States that have no freestanding facilities. Those States are Hawaii, Idaho, Iowa, Montana, Nevada, North Dakota, South Dakota, and Vermont. Over half of the freestanding facilities are also members of chain organizations. We note that very few hospitals belong to chains.

The next chart indicates the location of hospital-based dialysis facilities, which are more evenly dispersed across the States. Only 5 percent of the hospital-based facilities are private, for-profit facilities. While home dialysis is believed to be appropriate for some 30 to 40 percent of all of the patients, we find that it is now actually used nationwide by only 17 percent.

Senator DOLE. Is that primarily in remote areas where patients cannot easily commute to the clinic or the hospital? I mean, some areas in my State or Senator Baucus', there might be more patients in rural areas.

Dr. DAVIS. That is one of the possibilities, but it is not the only one. If you notice on this next chart, which indicates very clearly the percentage of home dialysis patients, there is a very wide, geographic variation in the home dialysis distribution. For example, the State of Washington has a home dialysis rate of 54.2 percent while the State of California has a rate of only 9.1 percent. I would also note two adjacent States—Illinois and Indiana—Illinois has a 6.2-percent home dialysis rate while Indiana has roughly 44 percent home dialysis in its program. So it is a product of a number of the other variables as well as access to a facility.

Senator DOLE. Well, I think in Illinois though they have been pretty well saturated with freestanding clinics. In my State, I think we have only four facilities and they are all hospital based. So there is a little more home dialysis. But in Senator Baucus' State almost half of all patients are on home dialysis.

Dr. DAVIS. Yes, sir, there definitely is a correlation between access to a facility and the numbers that go on home dialysis.

Senator DOLE. I guess the thing that I wanted to get to, is there a certainty that the people who have the need and can use home dialysis are aware of the service, I guess is what I am asking. Are there some people who never hear about home dialysis service, never get the message?

Dr. DAVIS. Yes. I read through the testimony from your previous ESRD hearing, and I noticed that some nephrologists indicated that one of the problems is the fact that some physicians have not been exposed to the home dialysis program.

Senator DOLE. And there isn't any alternative for dialysis that I know of. There could be some nutrition programs that might delay it.

Dr. DAVIS. No. I think that the only alternative for a number of patients would be transplantation.

Senator DOLE. Well, that is not widely used either.

Dr. DAVIS. No, it is not. However, we would certainly like to see that encouraged.

Senator DOLE. Maybe we could give tax credits for that, or something.

Dr. DAVIS. Let me go back to the summary. Currently medicare reimburses hospitals for reasonable costs. We believe that that is one of the reasons why they have no incentive—or little incentive—for efficiency. Freestanding facilities are reimbursed for reasonable charges up to a maximum of $138 a treatment. Nearly all of the freestanding facilities charge the maximum, and thus they keep the difference between their charges and the actual cost. We think that neither the program nor the patients have benefited from the lower cost in the freestanding facilities.

Our audit data show the median cost for home dialysis to be $97 a treatment.

Senator DOLE. Ninety-seven?

Dr. DAVIS. Ninety-seven. We believe that there are potential benefits from wider use of home dialysis that have not yet accrued to either the patient or the program. Therefore, we certainly intend to encourage home dialysis.

Senator DOLE. Well, do you in fact encourage home dialysis, and is there an ongoing effort to encourage dialysis, not because of lower cost, but because I assume it is beneficial in most cases?

Dr. DAVIS. We believe that our new proposed rate structure speaks to that particular issue. Presently, there is no incentive—in fact, there is a disincentive—for a physician to place a patient on a home dialysis program.

Senator DOLE. But isn't there some way to build an incentive into the program for home dialysis in order to benefit the patient?

Dr. DAVIS. We believe that the new rate structure, that is, a composite rate, does that because it will give an incentive for the facilities to maximize the number of individuals on home dialysis that they can handle.

Senator DOLE. But what incentive is there for the patient?

Dr. DAVIS. There are definite incentives for patients on home dialysis because patients tend to be rather dependent. This is true of any chronic condition, but it is particularly true with chronic renal dialysis patients who know that they are, in effect, wedded for life to the dialysis treatment program. We believe that sending individuals to a home dialysis program is useful from a psychological and emotional viewpoint, as well as a better tool for rehabilitation efforts. It is much easier for an individual who is on a home dialysis program to be rehabilitated and return to work than it would be if he had to travel to a precise location for his treatment.

Senator DOLE. I think there are a lot of advantages, but it seems to me it might be possible to provide an economic advantage, in addition to those advantages, if in fact there was a set rate paid to those who participate in home dialysis, which would be enough to purchase their equipment and supplies. And if they had anything left, they could pocket the difference. That is better than shoveling it out. These are taxpayers' funds. I think that is the point we want to make. They are not mine or yours, but they belong to taxpayers who are being asked to make sacrifices because of the economy. And it is obvious this is a very generous program to the providers. It has been, and still is, and probably will be for the next couple of years. So I think we ought to look at some way to, if you are going to have to pay for the service, maybe you can save money if you pay the person who is directly involved and who has a real interest in it.

I am taking up your time, but go ahead.

Dr. DAVIS. That is an interesting point. Let me just summarize. Our data was derived from audits of two samples of facilities. The first audits were for the cost of the in-facility dialysis in 38 freestanding facilities and 67 hospitals. Our second audits were for the cost of the home dialysis that were conducted in conjunction with the Inspector General's Office. We audited 25 of the largest home dialysis programs in the country. I would just refer to the Reconciliation Act of 1981 which clearly mandated a preference for a composite rate that would apply to both the in-facility and the home dialysis programs. This ESRD provision instructed us to give a greater incentive for home dialysis and to differentiate between the types of facilities.

Briefly, let me review our methodology. Our methodology uses as a departure point the median costs of home and facility dialysis for all of the facilities that were audited. These costs were then weighted by the proportions of hospital patients dialyzing in each location. For the hospital patients, 23.5 percent dialyzed at home, and 76.5 percent in the facility; and of the independent ESRD patients, 10.5 percent were at home and 89.5 percent were in facilities. The requirement for a differentiation between hospital and independent facilities, we believe, means that the hospital rate must be adjusted to account for only legitimate higher costs that were incurred by hospitals as a group. We, therefore, raised the hospital rate by $2.10 to account for the additional overhead costs that would result from the medicare hospital accounting requirements. We felt that there should be no adjustment for hospitals' generally higher costs of labor and supplies because we had no evidence to justify that. We then added 5 percent to the hospital rate to account for the possibility that the methodology may not have fully recognized all of the legitimate cost factors of hospitals or that there could have been some shortcomings in the audited data. And then, of course, there would be an area wage adjustment. After considering all of those factors, the computation gives you an average rate of $132 for the hospital-based facilities ranging from $114 to $148 after area wage adjustments; and, for independent facilities, an average rate of $128 (ranging from $109 to $143 after area wage adjustment). Our regulations provide for an exceptions process to allow for a higher rate for those facilities that have justifiable higher costs due to very specific criteria, such as an atypical patient mix, isloated essential facilities, some kind of an extraordinary circumstance (floods, fires, etc.) and educational costs. If the exception request is denied, the facility could appeal the denial.

Moving to physician reimbursement. Currently, the physicians are paid under two systems: the initial method and the alternative reimbursement method, better known as the ARM method. We think that these methods provide the incentive for the physicians to treat the patient in the facility rather than at home. To remove that disincentive, we are proposing to eliminate the initial method and to establish the physician's capitation monthly payments for both home and facility dialysis.

In terms of the auditing and claims processing activities, the contractors' workload, we believe, is going to be lighter because the proposed system will be much simpler for paying both the facilities and the physicians than the current system. Therefore, the contractors will be able to devote more resources to their audits. Although the contractor—intermediary—will review the exceptions request, I would like to point out that HCFA will make the final decisions on all exceptions.

In conclusion, we believe that the proposed regulation does meet the statutory requirements of the 1981 Omnibus Budget Reconciliation Act's incentive reimbursement provision. We think that the Federal Government will benefit through lower expenditures; facilities will benefit through potential for additional profit; and, the patients will benefit by more opportunities for home dialysis.

Senator DOLE. Thank you very much. And your entire statement will be made a part of the record, along with copies of the charts. What is the status of the renal nutritional study that Congress mandated in 1978?

Dr. DAVIS. This is a mandate that concerns both the National Institutes of Health and HCFA. The NIH has supported pilot research relative to the mandate. We have been in conversations with NIH and are now trying to decide what course of action we should take.

Senator DOLE. If you could furnish some more specific information for the record on that it would be helpful because I am interested in that.

Dr. DAVIS. I would be happy to for the record.

[The information follows:]

HCFA has met with representatives from the National Institutes of Health (NIH) to decide on the approach to take on the ESRD nutritional therapy study. It was agreed that NIH will first sponsor a conference to determine the state of the art. This conference will be conducted by the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases, on April 29-30, 1982.

Scientific clinical papers will be presented by experts in the field on the first day of the workshop. On the second day, participants will discuss the goals of a nutritional study in chronic renal disease failure and identify the specific methodologies, and techniques of such a study.

The participants will also discuss the scientific studies already completed in nutrition and renal disease. In addition, the workshop will address the various aspects of nutritional therapy in chronic renal failure as it relates to all relevant fields, e.g. nutrition, metabolism, nephrology, dialysis, clinical trails, etc.

The purpose of this conference is to assess the value of a nutrition regimen in the prevention or delay of onset of end-stage renal disease. This workshop will bring together authorities in the field to discuss the pros and cons of a feasibility study relative to nutritional therapy and the initiation of dialysis in end-stage renal disease.

Senator DOLE. Now as I understand—the Inspector General just testified—he does not believe that your proposed rates satisfy congressional intent to have the Department establish dual rates based on separate costs of both facility types. And I am not certain that I agree with your findings either. Can you explain how your proposal, which establishes rates based on the cost of all facilities, meets the legislative mandate to establish separate rates for hospital-based and freestanding facilities?

Dr. DAVIS. Yes. We considered several options. And of those several options, we felt that if we were to use a separate data base for both hospitals and independent facilities, that that would continue to recognize the inefficiencies that we believe have been developed as a result of the hospitals being paid on a retrospective cost base. By using a separate data base, there would not be an incentive for efficient management. We did not believe that we should build a prospective system from an inefficient retrospective cost base system. We wanted to maximize the potential for the marketplace in order to utilize the more efficient operations. We then thought about the possibility of using only the independent data and adding the overhead cost for the hospitals to that base. The General Counsel's opinion was that our data base would be much better if we used the sample that would be representative of the world universe. And so we used a combination of the data from both the hospital and the independents, and then added a $2.10 overhead differential for hospitals. We felt that this approach accounted for several factors. It recognized the incentive for efficiency. It also recognized the legitimate higher hospital costs that are different from the overhead component. In addition to that, we added 5 percent. Now, we could have, I suppose, had 110, 115, or 120 percent. The 5 percent increase was certainly a judgment factor. We felt that it was prudent to keep it as low as possible, and yet to allow for some component that would allow for the aging of the data. We tried to balance our fiscal concerns with our concerns for access to the program. There have been opinions expressed that the rate is too high, and there have been opinions expressed that the rate is too low. They conclude that we have compromised and found a position which assures minimal profit, but still guarantees access.

Senator **Dole**. Are you getting into all of these related organization questions where, in some cases, they may be structured just to pay more reimbursement to the Federal Government? I mean, the taxpayers have an interest in the money we spend. Do you have any ongoing investigation or audit?

Dr. **Davis**. Yes, Mr. Chairman.

Senator **Dole**. I am not trying to scandalize the program, but apparently they bought, what, five Mercedes Benz, one for each physician. Do you think that that is a reasonable cost that the Government should pay for?

Dr. **Davis**. No. I would point out that those particular facilities were under a charge based system and not a cost system. But we are concerned about related organizations. We are concerned about some of the other factors. I have asked the Inspector General's Office to work with us, once we get the new rate in place, to continue to do audits, and this would certainly be one of the areas that we are going to look at.

Senator **Dole**. Do you need any more authority? Could this committee give you more authority for audits or investigations?

Mr. **Kappert**. Mr. Chairman, in several previous considerations about related organizations, we asked for additional authority and we now have that authority. I think the problem will come primarily with respect to something that the GAO mentioned this morning. This is a very difficult and intense area to audit. You have to make a tremendous investment of both auditor time and, of course, the money to pay for that auditor time. The kinds of things that you are looking at are very complex. I think the Inspector General mentioned the fact that it may take as many as 2 years to really get to the kind of specifics that were mentioned this morning.

Mr. **Streimer**. Mr. Chairman, if I could add, many of the problems that were alluded to this morning were based primarily on the fact that over the last several years facilities have voluntarily completed a questionnaire that did not contain definitions of costs in terms of how we would like to see them defined. The program has recently issued new cost reporting documents with the necessary penalty statements and threats of prosecution for not filling the form out truthfully. And we will be able, for instance, to distinguish between what the program defines as reasonable cost as opposed to what a facility on its own may decide are its reasonable cost when submitted on a voluntary questionnaire.

Senator **Dole**. Thank you.

Dr. **Davis**. Mr. Chairman, I would like to point out, too, that we have in our new legislative proposal a request for sanction authority against facilities that do not complete the data. At the current time, the only sanction authority we have is to not pay that facility. We will be submitting in our legislative proposal a request so that we can reduce the reimbursement to the facility as a sanction method without stopping the access to the program itself.

Senator **Dole**. Is that legislation ready to be introduced?

Dr. **Davis**. That legislation will be submitted, yes.

Senator **Dole**. When do these new rates become effective?

Dr. **Davis**. The end of our comment period for the NPRM is April 13.

Senator **Dole**. You are not going to change them, are you?

Dr. **Davis**. I beg your pardon.

Senator **Dole**. There won't be any other changes? We can assume that these rates will become effective?

Dr. **Davis**. We anticipate that it will take us about 60 days to do the analysis of the comments on this particular proposal. Then we will publish it in the final. The rates will become effective upon publication.

Mr. **Streimer**. We think we can make July 1.

Senator **Dole**. When does the comment period start?

Dr. **Davis**. It was published February 12.

Senator **Dole**. It can't be effective April 12? Why do you wait until July 1?

Mr. **Streimer**. It will take us some time to analyze the comments and prepare a final regulation. And then it must wait 30 days before it goes into effect.

Senator **Dole**. Are there comments coming in now? I mean, is the analysis underway?

Mr. **Streimer**. Comments are coming in. They have been surprisingly slow. We usually get most comments on the last day.

Senator **Dole**. Well, if the independent facilities are efficient, and provide treatment for $103 as GAO's review suggests, why shouldn't the ratesetting methodology be adjusted to lower the proposed rate for independent facilities to account for the deficiencies and audit data for those facilities? GAO suggested that this morning and so did the Inspector General.

Dr. **Davis**. Mr. Chairman, I have some concerns about the GAO's statements relative to their audited data. They indicated, or their presumption was, that we agreed with them. We don't agree with that. And I would like Mr. Streimer to discuss that in more detail.

Mr. **Streimer**. Yes. I think our data, based on the audits that HCFA performed, as the chart indicates, showed a median independent facility cost of $108. Before I speak to the GAO points, I would like to mention that that is the bare bones production cost of the service. Independent facilities, which are primarily proprietary, need to pay income tax, property tax, and local taxes of several varieties. They also require a return on their capital investment, and they generally require some funding for future capitalization and expansion. So in the context of what the $108 represents, that is the production cost of a service, absent any marketplace or tax considerations, that a proprietor of that facility would face.

Senator **Dole**. We just passed a tax bill last year that will help all those people to speed up depreciation. We also lowered the top tax rate from 70 to 50 percent.

Mr. **Streimer**. That is a very interesting point because the $108 reflects the medicare rule which does not permit the speeding up of depreciation. The medicare rule allows only straight-line depreciation. So, again, the $108 is the bottom line. Now, as to the number itself and the GAO analysis, if you would accept for a minute that GAO's numbers of $5.50 per treatment are accurate—and we do have some problems with those—the net effect on the reimbursement rates would be only $2 per treatment in the independent and the hospital-based setting. Of the 13 audits that the GAO did, 46 percent of their total adjustments came from one facility. In addition, that one facility accounted for 38 percent of the treatments over the range of the 13 facilities that they looked at. It is important to note that we did not construct the median rate of $108, the median cost of $108, based on looking at everyone and throwing all their costs into a pool and dividing by total treatments. We gave each facility in the sample an equal chance for its own experience to affect the rate. In other words, each facility had its own entry. The GAO numbers were not computed in that fashion.

Senator **Dole**. We can get into that later, but we do want the facts. Whether you agree or disagree, I think it is important because if the median cost is too low and you think it is not realistic, then we ought to have that information. But I would hope we are all working for the same government. And if in fact there can be adjustments that provides quality for the patient, and at the same time reduce the cost of the program and still allow a reasonable profit, then that ought to be the goal. I think the patient care ought to be first. But I think anyone would agree—and I assume you would—that this is a pretty loose program.

Mr. **Streimer**. In terms of the way it has been operated historically, I would agree, sir.

Senator **Dole**. Yes. I need to step next door to see Secretary Regan a minute, but Senator Baucus has some questions. There is just one question I would like to have answered for the record. I understand that pediatric patients require more care, longer care. Is there some allowance made for that in the rates that are set? Now, you can answer that for the record.

Dr. **Davis**. Yes. We have an exceptions policy, and we would anticipate that the pediatric facilities would be filing for that.

Senator **Baucus**. Dr. Davis, as I understand it, the purpose of the new regulations are to encourage more home dialysis. Is that correct?

Dr. **Davis**. That is right.

Senator **Baucus**. As I understand the proposed regulations though, they will not provide home patients with an incentive to continue to receive dialysis at home—because of the way home patients will be reimbursed. What I am trying to drive at is whether in fact home dialysis will be encouraged. And as I understand it, under the new regulations reimbursement will be made to the patients. And as I understand it, the patient will also pay 20 percent of the full payment requirement. It seems to me that if the reimbursement for both home and facility dialysis is the same, there is no longer an incentive in the regulations for a patient to go on home dialysis. He will be paying more because the full reimbursement rate will be higher; and he still has to pay 20 percent, 20 percent of an amount more than what he was paying before. So it just seems to me that we are losing some of that incentive to dialyze at home.

Dr. **Davis**. Yes. I think that what you are referring to are the patients that are already on home dialysis. Because, for the new patients that come into the program, they would, we hope, be referred to a home dialysis program. For those patients that are already on home dialysis, we have an exception that allows for them to continue to buy their supplies and equipment without having to go through the facility. Mr. Streimer, would you like to add to that?

Mr. **Streimer**. Yes. The program has always permitted individuals to operate freely in the system, that is, buy their own supplies from whatever supplier they choose, or to associate with a facility. The people that are on home dialysis now that operate freely in buying their supplies and their machines on their own will continue to do so. New patients who come into the program will also be able to operate in that fashion if they so choose. We expect, though, that most new patients will affiliate with a facility—either a hospital-based facility or an independent facility—and receive all their supplies and equipment and medical advice through that facility.

Dr. **Davis**. I would also like to point out, Senator Baucus, that 39 States have a kidney program that helps patients with their financial liability.

Senator **Baucus**. As I understand it though, new patients will get the same rate regardless whether they are going to go home for dialysis or whether they go to a facility. That does not seem to be an incentive for home dialysis.

Mr. **Streimer**. Again, it would depend on whether the individual operated freely within the system as his own purchaser or whether the individual associated with a facility.

Senator **Baucus**. Do the proposed regulations also tend to eliminate the 100-percent reimbursement provision on home dialysis machines?

Dr. **Davis**. The elimination of the purchase of the home dialysis machine? Yes.

Senator **Baucus**. Why? This is the 100-percent reimbursement incentive for home dialysis?

Mr. **Streimer**. Well, I don't think the book is closed on that subject yet. Currently, there are 750 machines that have been purchased around the country on the 100-percent arrangement. Most of those machines were machines that preexisted the legislative change. In other words, people just converted machines they already had to the 100-percent arrangement. We have gotten a number of complaints from the facilities that there is too much bookkeeping and recordkeeping required. In addition, we do not believe that that particular methodology is supportive of our overall composite rate structure, where we would prefer that for the mainstream patient, the facility be responsible for all supplies and equipment. The facility would buy the machine and furnish it to the patient, and the facility, in exchange, would be paid the incentive composite reimbursement rate.

Senator **Baucus**. But still the effect of eliminating that provision would be a discouragement, not an encouragement to home dialysis, wouldn't it?

Dr. **Davis**. We do not believe that it would.

Senator **Baucus**. Again, why? I don't understand. If you eliminate that, why not——

Dr. **Davis**. Well, I think, Senator Baucus, you are presuming that all patients who go on home dialysis would be——

Senator **Baucus**. I am not saying all. I am just talking about the incentives here.

Dr. **Davis**. Our presumption is that there is a large number of individuals who are on home dialysis who would not be using a machine. For those that do, our experience for the last couple of years clearly indicates that there has not been a significant interest in moving into the purchase component.

Senator **Baucus**. What do you tell patients who are worried that these new regulations will result in perhaps closure of facilities or cutbacks in service, and maybe in taking the other side of the coin, forced use of home dialysis where it is unsafe? What is your answer to those worries, legitimate worries and concerns the patients have?

Dr. **Davis**. I can understand where the patients have become frightened, and I think that is unfortunate. I suspect that there has been some attempt to educate them to think that way. But our concern has been that we have an exceptions process for those facilities that are single, isolated facilities. We will certainly encourage them to utilize the exceptions process if they think that the rate is too low. We have said all along that we believe that we have to balance fiscal prudence with assurance of access. If a single facility closes in an area where there is competition around, then I think, you know, we cannot guarantee that there wouldn't be some closures. But, on the other hand, if it is a sole source in an area, certainly they would be entitled to an exceptions process. I think, too, that physicians are expected to use their best judgment in terms of whom to refer for a home dialysis program. I don't believe that they will make injudicious decisions that relate to that. Certainly, our concern is for the patient's welfare and well-being, and we will continue to guard that.

Senator **Baucus**. With respect to physicians' fees, is it true that physicians are reimbursed at the same rate, whether the patients are in facilities or receiving home dialysis treatment? Is that correct?

Dr. **Davis**. That is our proposal under the NPRM. We want to provide an incentive for the physician to refer more of the patients to home dialysis.

Senator **Baucus**. How did you come up with the $184 payment level? Why not $150 or $200? How did you arrive at $184?

Mr. **Streimer**. We took the—maybe I should explain where we are now.

Senator **Baucus**. All right.

Mr. **Streimer**. Where we are now is an average payment rate of $220, which ranges from approximately $180 up to $260. That rate is based on 20 times a brief followup office visit. There is a relative value code of 90040. Twenty times the reasonable charge for that code in an area represents the current alternative reimbursement method, the capitation method. That is the computation of that amount. There is not an expectation that a physician will see a patient 20 times in that month. Under our new proposal, we are taking 12.4 times the brief followup office visit and adding to that the charge for one monthly comprehensive physical examination. We then take that amount and composite it with the lower amount for home dialysis, which we currently pay at a 70-percent rate. The end result of that is $184 on average, which will vary from area to area, based on what the customary charge is for the brief routine followup visit and the monthly physical examination.

Senator BAUCUS. As I understand the charts here, I think it is 45 percent of the patients in my State of Montana have home dialysis.

Dr. DAVIS. That is right.

Senator BAUCUS. Whereas, in California it is 9 percent.

Dr. DAVIS. That is right.

Senator BAUCUS. Does that imply that Montana patients are getting poorer treatment?

Dr. DAVIS. No, sir. I think that the decision for home dialysis, as I indicated earlier, is based on several factors, one of which is ease of access to a facility. I would point out that there are no independent facilities in Montana and, to the best of my knowledge, four hospital-based facilities in Montana. Knowing the rather large distances to be traveled there, I would suspect that the patients themselves have in many cases encouraged the home dialysis program.

Senator BAUCUS. But you are telling me that Montana renal patients do not receive poorer service?

Dr. DAVIS. I do not believe that home dialysis is a poorer service, no, sir.

Senator BAUCUS. All right. Now, is it true that home dialysis tends to be cheaper than the facility dialysis?

Dr. DAVIS. Home dialysis is cheaper than in-facility dialysis, yes.

Senator BAUCUS. Can I then infer that, because of a lower California home dialysis rate, we are paying too much to California if home dialysis treatment is no better or no worse than facility dialysis?

Dr. DAVIS. I think that is an inference that one could agree with. We believe strongly that we should aim at between 20 to 40 percent of the patients on home dialysis. It is certainly clear to us that this is true for selected States with very large populations. Yet, there are a large number of facilities that do have ease of access, as well as positive physicians' behavior in terms of referrals to home dialysis. We have not been able to accomplish the degree of home-based dialysis that we would like to see. The home dialysis program is particularly important because it does give the individual patient a sense of independence.

Senator BAUCUS. Well, I find a little curious your statement, at least I imply from your statement, that in every case, you know, a person who is receiving facility treatment could without any lower health care treatment——

Dr. DAVIS. No, Senator Baucus, I did not say in every case. I said that between 20 and 40 percent of patients could go on home dialysis.

Senator BAUCUS. So between 20 and 40 is 30, so you are implying that maybe a certain percentage of Montana patients are in fact receiving poorer care?

Dr. DAVIS. No.

Senator BAUCUS. I am just trying to find out what you really think here.

Dr. DAVIS. I would like to see many more patients go to a home dialysis program. The percentage that are on home dialysis programs, we believe, should be an average. It should certainly be much more than it is now. If you think back to 1972, 40 percent of the patients were on home dialysis programs. For European countries, there is a much larger percentage on a home dialysis program. In Canada, I believe it is 39 or 49 percent, as it is in Australia and some of the other countries. So I think that physicians' behavior, in terms of referral, is one of the reasons for whether an individual is dialyzed in a facility or not. That is a judgment factor that is based upon the severity of the illness of the patient, the ability of the individual to learn home dialysis techniques, as well as the incentive system.

Senator BAUCUS. I just have one more question to ask, and that goes to the payment rate for freestanding facilities. As I understand it, your $132 payment rate for hospitals did not take into account hospitals' generally higher cost of labor because you say that you have no evidence that such excess costs are justifiable for hospitals as a class of providers. Yet, I understand you added those very same so-called unjustifiable costs when you calculated your rates for freestanding units. I am wondering why you can logically not include unjustifiable costs, in your words, for hospitals, yet use them in determining freestanding facilities' rates.

Dr. DAVIS. Senator Baucus, I am not clear what you mean by "adding unjustifiable cost."

Senator BAUCUS. The ones, as I understand HCFA regards as unjustifiable, are not included in determining rates for hospitals.

Dr. DAVIS. The case mix component is the subject of much discussion. There is a $20 labor component difference that we identified between the cost for the freestanding and the cost for the hospital-based facility. We have not been able to determine that there was a significant difference in patient mix or in complexity of the cases for the hospital versus the freestanding. That is why we said in our exceptions process that if a hospital does have evidence that it has an exception, then they should submit that to us and we would consider it.

Senator BAUCUS. But do you include some of those unjustifiables in determining the freestanding facility cost?

Dr. DAVIS. There is a labor component in there, but we consider that it was a justifiable component. The spread between the labor component was what we did not add in.

Senator BAUCUS. Thank you very much.

[The questions and answers follow:]

Q. 1 During your testimony before the Subcommittee you agreed to submit certain information for the record. Please provide the following:

-- 1982 program costs in 1974 dollars.

-- current status of the renal nutritional study mandated in 1978 and a timetable of actions taken to date by HCFA and NIH.

A. Regarding 1982 ESRD program costs, the value of $1.8 billion in 1982 is approximately equivalent to $1.2 billion of expenditures in 1974 program dollars. This $1.2 billion value takes into account the change in population and mix of services that have occurred from 1974 to 1982.

Regarding the renal nutritional study, HCFA has met with representatives from the National Institutes of Health (NIH) to decide on the approach to take on the ESRD nutritional therapy study. It was agreed that NIH will first sponsor a conference to determine the state of the art. This conference was conducted by the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases, on April 29-30, 1982.

Scientific clinical papers were presented by experts in the field on the first day of the workshop. On the second day, participants discussed the goals of a nutritional study in chronic renal disease failure and identified the specific methodologies, and techniques of such a study.

The participants also discussed the scientific studies already completed in nutrition and renal disease. In addition, the workshop addressed the various aspects of nutritional therapy in chronic renal failure as it relates to all relevant fields, e.g., nutrition, metabolism, nephrology, dialysis, clinical trials, etc.

The purpose of this conference was to assess the value of a nutrition regimen in the prevention or delay of onset of end-stage renal disease. This workshop brought together authorities in the field to discuss the pros and cons of a feasibility study relative to nutritional therapy and the initiation of dialysis in end-stage renal disease. A full report of the conference will be provided to the Secretary for transmittal to the Congress.

Q. 2 Since very few hospitals belong to chains, and hospital-based facilities *provide lower volumes of treatments,* is it possible that higher supply costs are justified because volume purchasing and reuse is not economically feasible?

A. Reuse of dialyzers is economically advantageous regardless of the size of the facility. Also, from the audited data, we found only a moderate difference in the supply costs of hospitals vs. independent facilities. Most of this difference was probably due to the fact that while 25 percent of the independent facilities reused dialyzers, only a little over 1 percent of the hospitals chose to reuse.

Our review of audited data indicates that there is only a moderate difference (about $4 per treatment) in the costs of hospital-based and independent facilities. This is probably due to dialyzer reuse differences as indicated above.

Q. 3 When asked whether HCFA had any ongoing investigation or audit of related organizations in the ESRD program, you answered in the affirmative. Please describe those audits or investigations.

A. Independent ESRD facilities often are owned or managed by related organizations. When intermediaries are directed by HCFA to audit these independent facilities, a review and evaluation of the related organization's operations will also be performed. Hospital-based facilities are audited regularly as part of the Medicare program's review function.

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Q. 4 As you stated, the composite rates are to provide incentives for home dialysis. Since hospital-based facilities have been able to achieve a 24 percent home dialysis rate and you report that the average rate is 17 percent nationwide, why was a rate as low as 10-1/2 percent, the current rate for independent facilities, selected as the basis for providing an incentive for those facilities -- why not at least use the national rate?

A. In constructing our proposal we considered many options, one of which was selecting the national average of patient dialysis at home (17 percent) as a weighting factor for both hospital and independent facilities. However, we decided that the most appropriate method would be to tailor the composite rates to the group experience of both hospitals and independents. In this way, efficient facilities, both hospitals and independents, should benefit by exceeding the average home percentage experience of other facilities in their same group.

Q. 5 The proposed rates would reimburse 78 percent of the hospital-based and 24 percent of the independent facilities in the audit sample at less than allowed costs. Doesn't this, as some have charged, constitute an entitlement cut which will clearly lead to a contraction of facility capacity? Furthermore, how does HCFA intend to assure that the quality of care provided patients will not suffer? How does HCFA intend to ensure that the delivery of dialysis services is not interrupted and the lives and safety of patients is not threatened?

A. No, we do not believe that this constitutes an entitlement cut. We estimate that 46 percent, not 78 percent of hospital-based dialysis facilities and 28 percent of the independent facilities would be reimbursed at less than the current costs. While we cannot guarantee that no facilities will close, our exceptions process will deal with problems encountered by isolated facilities. In addition, we anticipate that "facility" mergers might occur which would continue efficient and high quality delivery of care.

We will maintain our facility surveys of health and safety standards as well as quality to make certain that quality of care is not reduced below program standards. If problems occur we will work with facilities to resolve their problems. However, only facilities that meet quality of care requirements will be allowed to continue to participate.

Q. 6 The proposed regulations would allow an exception when a facility, compared to average facilities, has a mix of patients requiring intensive services, special procedures or supplies. What do you intend to define as an average facility? And how will you determine when facility standards are comparable and patient mixes are similar?

A. Our current data does not enable us to define such a standard. We have attempted to study various aspects of this question (e.g., staff/patient ratio) and the medical community itself cannot provide standards. It seems that almost every facility believes its patients are atypical.

We recognize that defining a standard patient mix is very difficult due to the large number of variables. Age, secondary diagnosis and complicating conditions are all considerations, but to date we have not been able to obtain a consensus for defining a general standard.

For example, some aged patients may require extraordinary care and some may not. A particular secondary diagnosis may generally involve special care, but in other cases may not. The one case that we have some experience with is pediatric patients, and there are some facilities that treat an extraordinary percentage of these patients. We welcome suggestions and any assistance from the medical community for developing these standards. Because we do not want to ignore the possibility that some facilities may have atypical patients, we incorporated the authority to grant an exception for an atypical case mix.

Q. 7 I understand that it can cost about $12,000 to place a patient on home dialysis. How will small, independent facilities--mom and pop type operations--be able to finance the equipment initially needed for home dialysis if the 100 percent reimbursement option is discontinued?

A. It does cost about $12,000 to purchase all the necessary equipment to place a new patient on hemodialysis. However, the majority of new home patients are not on hemodialysis but are opting instead for Continuous Ambulatory Peritoneal Dialysis (CAPD), which has no equipment costs. Further, our review of home dialysis costs determined that home hemodialysis costs approximately $87 per treatment, $13 of which are equipment costs while the remaining $74 are for supplies, home support and administrative costs. We propose to pay independents approximately $128 per treatment and hospitals $132 per treatment under the composite system. We expect hospitals and independent facilities to act like any other business in this respect. If they do not have the cash outlays to purchase the needed equipment, a facility may want to borrow the money to purchase the equipment.

Q. 8 Were any adjustments made to the audited costs data to reflect dialyzer reuse? If so, what degree of reuse is reflected in the HCFA cost data?

A. No special adjustments were made to reflect dialyzer reuse. We instructed the auditors to report costs that the facility incurred in providing outpatient maintenance dialysis treatment. The audits found that 25 percent of the independent facilities reused dialyzers but only a little over 1 percent of the hospital-based facilities reused dialyzers.

Q. 9 Did any of the costs disallowed by HCFA represent goods or services essential to doing business or essential to providing quality care?

A. No. The standard Medicare principles of reimbursement were the basis for the ESRD audits of in-facility dialysis costs. Hospitals have been subject to these principles since the inception of the Medicare program. We believe they are an equitable method of determining the costs of providing health care. Further, the largest areas of adjustments were owners' compensation and bad debts, neither of which would affect the quality of care provided by these facilities.

Q. 10 Evening dialysis is important to many patients who want to work and yet evening dialysis is likely to be the first area where a facility can cut costs. Shouldn't some level of evening dialysis be mandatory so that rehabilitation remains a viable option for all patients?

A. No. There are no current regulations on "evening dialysis," and we have no plans to implement any. We would expect that if a sufficient number of patients require evening dialysis, facilities would react to this market demand and provide such care on a facility-by-facility basis.

Q. 11 Could an atypical case mix include patients who are medically qualified for home dialysis, but cannot become home patients for social or psychological reasons? If so, who makes that decision and will HCFA grant an exception on that basis?

A. We do not believe that "social reasons" are an appropriate reason to approve an atypical case-mix exception request. That is, if by "social reasons" you mean, the poor uneducated and/or disadvantaged portion of the dialysis population. Traditionally, the rural areas of the country, rich and poor, have had a much larger percentage of patients on home dialysis and while presently not many of the urban poor are on home dialysis, we feel that this is due to the financial incentives for in-facility dialysis that are present in the current reimbursement regulations. Even today there are pockets of the urban poor that have large home populations. Examples of this can be found in Camden, New Jersey and Chicago, Illinois. Further, there is a recently developed form of home dialysis, CAPD, which does not require any technical apparatus and can be learned quickly. It does not require the assistance of another person, so a patient is truly self-sufficient.

Q.12 Is it reasonable to expect hospital-based facilities to immediately adjust to the new rates, and once they are able to do so, is it possible that End-Stage Renal Disease (ESRD) costs will simply be shifted to inpatients?

A. We believe that the majority of hospital-based facilities will be able to adjust to these new rates. Incentive reimbursement is not something that has emerged suddenly. The End-Stage Renal Disease (ESRD) Program Amendments of 1978 (P.L. 95-252) were enacted in large part to alleviate the problem of rapidly increasing expenditures. Further legislative changes concerning the ESRD payment system were made by the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35). As a result, hospitals have been aware that HCFA has been developing a prospective ESRD reimbursement system for some time and hopefully, have been planning accordingly. You must also remember that hospitals will receive the composite rate not only for their in-facility patients but also for their home patients. If we assume that the cost of providing all types of home dialysis is $97 and the average hospital payment rate is $132, then on the average, hospitals will make $35 per treatment profit on each home dialysis treatment that they supervise. In addition, 24 percent of hospital patients are on home dialysis. The percentage of patients on home dialysis should increase over time, further relieving any financial pressure on hospitals. Further, we have no reason to believe that ESRD inpatient costs will increase as a result of implementation of the composite rate.

Q. 14 If the independent facilities are efficient and can provide treatments for $103 or less as the General Accounting Office's (GAO) review suggests, why shouldn't the rate-setting methodology be adjusted to lower the proposed rate for independent facilities to account for the GAO and Inspector General identified deficiencies in audit data?

A. We believe the proposed rate for independent facilities is necessary to provide sufficient reimbursement to recover costs, provide a reasonable return on investment and assure that beneficiaries will have access to care.

Q. 13 In 1979, the Inspector General (IG) found that independent facility costs could be inflated through related organization transactions. The IG later expressed concern about the adequacy of your audits on that basis. Now the General Accounting Office tells us that related organization transactions seriously overstate costs. Why didn't your audits address this issue? And how do you intend to deal with these findings?

A. We did discuss the issue of related organizations in our audits of in-facility dialysis costs.

We instructed the field auditors to examine the issue of related organizations. In fact, we made related organizations an audit step in the audit program. We also audited the Home Offices of National Medical Care (NMC) and Dialysis Clinic, Inc.

As is the case with most audit activities, limited resources were available to conduct the audits in terms of staff hours. However, given this constraint, we believe the audits provided sufficient data on costs for rate-setting purposes.

Q. 15 A study undertaken by the Committee staff indicates that certain diagnoses are associated with hospital rates of admission and lengths of stay which are greater for patients that dialyze in a hospital-based facility. I understand that your studies also indicate differences in case mix between patients dialyzed in hospital-based and independent facilities. Do you feel it is still prudent to base the rate-setting methodology on the assumption that there are no differences?

A. In my testimony of February 24th before the Intergovernmental Relations and Human Resources Subcommittee, House Committee on Government Operations, I stated that we are taking another look at the data to determine the case mix. I anticipate that this in-house study will be available by the end of May and I will be pleased to share the results with you.

Senator BAUCUS. Senator Durenberger?

Senator DURENBERGER. Thank you very much. I have an opening statement which, without objection, will be made part of the record. But on that last point, Senator Baucus, are you referring to the way costs are determined in a hospital as compared to a freestanding center? Is this the difference in the operation?

Senator BAUCUS. What I am getting at, Mr. Chairman, is trying to determine the ultimate way to correct reimbursement rates. And in looking at the proposed rates, proposed regulations—proposed reimbursement rates—on the surface anyway—there may be some explanation—it looks like some of the items that HCFA does not regard as justifiable and therefore not included in hospital costs, but may in fact be included as the so-called unjustifiables included in freestanding facilities bases to determining what their reimbursement rates should be. That was my concern.

Senator DURENBERGER. I want to make sure I understand what you meant by saying that we should aim for 20 to 40 percent patients on home dialysis. Does that mean we as a purchaser should be negotiating for that percentage, or does that mean that 20 to 40 percent is what you believe to be the medically determined capacity for home dialysis among all kidney patients?

Dr. DAVIS. There have been a number of testimonies in the past relative to what percentage we should have on home dialysis. I think it is a physician's judgment. It is obvious to us that not all patients can go on a home dialysis program. The figure of 20 to 40 percent is simply a range we should aim at now. From my point of view, the closer to the 40 percent, the better, recognizing that in some States right now we are rather low. We have a long way to go.

Senator DURENBERGER. What do you mean when you say "We should aim?" Does that mean it is our responsibility to put people on home dialysis?

Dr. DAVIS. The composite rate that we have designed here is clearly an incentive for more individuals to go on a home dialysis program. Again, I think that any other techniques that we can use to educate the patients as to the availability of home dialysis programs is another important component.

Senator **Durenberger**. The incentive here is that the provider, whether it is a free standing or a hospital, makes money by putting people on home dialysis.

Dr. **Davis**. That is correct.

Senator **Durenberger**. All right. Did you consider giving the money to the patient and letting the patient make the judgment between the options?

Dr. **Davis**. We did not, Senator.

Senator **Durenberger**. Would you be willing to explore that?

Dr. **Davis**. I would be happy to explore it.

Senator **Durenberger**. Can you see any major obstacles with approaching reimbursement from that direction?

Dr. **Davis**. I would have to take that under consideration and study it before I could make any objective determinations. When you look at a voucher system there are always a number of factors in terms of how it would be implemented. But we would be happy to consider it.

Senator **Durenberger**. Thank you. In addition, is there any reason why you couldn't just set up a separate rate for pediatric dialysis?

Dr. **Davis**. In order to get a data base on which to do that, we would have to go back and do an audit of all of the pediatric facilities.

Mr. **Streimer**. Senator, that is correct. And there is no pediatric facility that has not come forward and demonstrated what its exceptional nursing costs are that has not been given an exception. We do have information that would indicate there clearly is a difference in the treatment of that patient as opposed to the general patient.

Senator **Durenberger**. Well, then what is the problem? If, in your judgment, pediatric dialysis is more expensive, then what is wrong with taking the next step and setting up the separate rates?

Mr. **Streimer**. There are so few facilities that provide pediatric dialysis. We would be hard pressed to establish separate rates, because Johns Hopkins Hospital, in Baltimore, might get $75 extra per treatment for a pediatric patient; we would not want to pay that to a hospital in Florida that may only need $18 a treatment more. The data is not there for us to firmly fix an amount for a pediatric patient.

Senator **Durenberger**. But you have all the exception data, so you could come up with a prospective rate. Even if that rate was less than the $75 Johns Hopkins needed, they could still apply for an exception. But at least the number of exceptions would be reduced and there would be a general recognition of the increased cost of pediatric dialysis.

Mr. **Streimer**. I would expect that after a year or so under the program of hearing new exception requests, that we may indeed be able to do that. In addition, we mentioned earlier that we do have new cost reporting vehicles that providers will be required to complete, and we ought to get a better handle at that time on fixing a specific amount for an exceptional instance.

Senator **Durenberger**. All right.

Dr. **Davis**. We recognize that there has been some question about the data base, but we utilized the best available data. We have been trying several years to meet the congressional mandate to move to a prospective system. We really felt that we would do better to use the data that we had in house from the recently completed audits rather than to try as the GAO and IG suggested, to go back and do a full scope audit. A full scope audit we have estimated would cost us an additional $3 million plus 6 months in time. For each month we would be losing approximately $11 million. So that would really be a cost factor of some $68 million for us to go back and do additional audits at this point in time. I think the more reasonable and rational approach is to implement our proposed system and then to keep very close track of it for 1 year. I have asked the IG's office to work with us in terms of doing a specific audit relative to some of the areas. With this audit in conjunction with our own better cost data, we should then be in a position to reassess that rate. If it is imprudent, that is, too much or too little, we will adjust it at that point in time.

Senator **Durenberger**. Well, I want to encourage that. I am sure we are going to hear some criticism of the prepared rates today, but my sense is that you are at least moving in the right direction. It may take 2 or 3 years to reach the right balance between patient interests, which we all put first, and reimbursement to providers. We cannot expect miracles or a perfect system in a short period of time, but I think you are moving in the right direction and I compliment you for that. Senator Baucus do you have any questions?

Senator **Baucus**. I have a question, Mr. Chairman. I know you want to hurry up, but I will make it brief. As I understand the rationale for the higher hospital reimbursement compared to the free standing is that to some degree anyway hospitals have sicker patients. Is that correct? Is that one reason why hospitals——

Dr. **Davis**. We do not have the data that would indicate at this point in time that they are sicker. We have had two conflicting reports inside HCFA, and, even as I speak, we have a group of research people looking at our own data base to try to determine if there is a difference in case mix. At the moment, we do not have data that would indicate that there is. I would also like to point out that in the last Senate ESRD hearing there was a statement made by a noted nephrologist that the hospitals should be asked to submit the data to prove that they had a difference that was related to additional needs for staffing requirements.

Senator **Baucus**. I asked the question because I am confused at a figure on one of your charts—that is the rate calculation chart—which shows that in calculating the hospital rate that 23 percent of the hospital patients are patients at home.

Dr. **Davis**. That is right.

Senator **Baucus**. And in calculating the independent rate, only 10 percent of the independents are at home. Why the lower independent rate?

Dr. **Davis**. We considered—and we could have set a national home dialysis rate of some kind—we felt that it would be more prudent for us to utilize the current rate that we knew that both were already on in terms of giving them an incentive to increase it. We felt that the incentive reimbursement method would enable each of the facilities to be able to save additional moneys under the current home dialysis rates. If we were to set a national rate for home dialysis, it would have been a difficult judgment.

Senator **Baucus**. Well, why do the independents send fewer patients home?

Dr. **Davis**. I think that is a question you ought to ask them.

Senator **Baucus**. Well, I am asking you.

Dr. **Davis**. My presumption is that there has been no incentive for the home dialysis.

Senator **Baucus**. But I am comparing it with hospitals. Why do hospitals send more, a greater percentage of patients home compared to the independents?

Dr. **Davis**. The hospital is on a different payment system at this moment in time. They are on a retrospective cost-base system. I mean, they cannot keep anything extra. We pay them what they say their reasonable cost is. In the case of independents, they are on a reasonable charge system; they set a charge and they can keep the difference.

Senator **Baucus**. There is an incentive for them to keep patients.

Dr. **Davis**. It could be interpreted that way.

Senator **Baucus**. Do you interpret it that way? I see two or three heads nod. [Laughter.]

Dr. **Davis**. It is clear that for those areas where there is a large number of independent facilities there is a significant lack of home dialysis. So one can infer from that.

Senator **Baucus**. Thank you very much. Thank you, Mr. Chairman.

Senator **Durenberger**. Thank you. I haven't seen all the charts and I'd certainly appreciate it if you would leave them here.

Dr. **Davis**. I would be happy to leave them all here.

Senator **Durenberger**. Others may want to refer to them from time to time.

Dr. **Davis**. Let me just point out that this chart here is a complete map of all dialysis facilities.

Senator **Durenberger**. Thank you. Unfortunately, it's blocking the view of somebody back there. Perhaps we could move it?

Dr. **Davis**. I am sorry about that. We will move them, but we will leave them.

Senator **Durenberger**. Thank you all very much. Our next panel consists of Dr. Richard Freeman, president, National Kidney Foundation, from New York; Dr. John Newmann, president, accompanied by Miss Margaret Diener, executive director, National Association of Patients on Hemodialysis and Transplantation, from New York; and Nancy Sharp, who is president, accompanied by Julianne Mattimore and Kathleen Smith, cochair, government relations committee, American Association of Nephrology Nurses and Technicians, from Pitman, N.J. Dr. Freeman, let's begin with you.

STATEMENT OF DR. RICHARD M. FREEMAN, PRESIDENT, NATIONAL KIDNEY FOUNDATION, NEW YORK, N.Y.

Dr. **Freeman**. My name is Dr. Richard M. Freeman—in contrast to Dr. Richard B. Freeman—from New York. My only car is a 4-cylinder Omega. [Laughter.]

That is a private joke that you missed, Senator.

Senator **Baucus**. I don't know if that is bad because I am thinking of buying a 4-cylinder Omega. [Laughter.]

Dr. **Freeman**. I represent not only the physicians involved with a kidney and urologic disease but the nurses, dialysis, technicians, social workers, dietitians, lay volunteers of the Foundation as well as patients, and I came from a quarterly meeting of the National Kidney Foundation in which we reviewed the regulations in great detail. We are concerned about the regulations, and part of our concern has to do with methodology rather than output. We think that the rates appear to have been made on an effort to save a specific amount of money rather than an attempt to evaluate the cost data as has been found. The development of cost data in general with the end-stage renal disease has been the bain of its existence and that problem appears to continue. There are, however, several specific areas that we are concerned about. We are worried about dialysis in rural areas, for example. There is recently an analysis from network 8 which includes Iowa and Nebraska which I will give to you. This analysis reveals that the network which treats 1.2 percent of the dialysis population would be responsible for 2.8 percent of the cost savings, and presumably other rural areas would be similarly affected. We are concerned a little bit about the references to continuous ambulatory peritoneal dialysis which is often called CAPD. It has still not really been established where this is going to stand in terms of the total treatment program. However, this procedure has been very important in terms of the increase of home dialysis over the past 2 to 3 years. Nearly all the increase in home dialysis has come from this population. And we still lack good cost data in terms of how that is going to turn out. We are not sure if that is going to cost more or less than home hemodialysis, and that is critical in terms of how we think of that particular procedure.

And, finally, as a physician, I remain anxious about any regulations which might theoretically lead to more strict selection of patients for this life saving dialysis treatment. About 3 weeks ago I saw in my renal clinic a 65-year-old woman who I had first seen in 1972, and I looked back at the note that I had written in 1972, and I had said, "This is not an ideal candidate for dialysis or transplantation because of her age and cardiac disease." Several months later I wrote another note which said, "Perhaps we can maintain this patient with peritoneal dialysis until funds become available in July 1972." This particular woman has lived 9 years since that time. She has never been hospitalized during that whole 9 years. If anything, she looks healthier now than she did 9 years ago. And I guess the reason I emphasize this is because as physicians were not always able to select those people who will thrive or will not thrive, and those of us who were forced to do this 10 or 15 years ago do not look with favor with the idea that that might happen in the future. For that reason, the National Kidney Foundation is willing, indeed anxious, to help the Government in any attempt to decrease the cost of the program in any way which does not jeopardize patient care. Perhaps a national task force established specifically to attack this issue could be formed.

I was pleased that Senator Dole did notice in the information given by Carolyne Davis that the cost per patient actually have decreased since 1973, and this development is related to the fact that we have had success. The patients are living; they are not dying. And I guess that kind of success was not predicted 10 years ago. I would like to point out also that a workshop on the impact of nutrition on renal disease is being organized through the National Institutes of Arthritis, Diabetes, Digestive Kidney Diseases. This will occur at the end of April.

And, finally, I would like to say that cost containment is occurring now throughout the country. The implication may be that that is not happening. In the State of Iowa from which I come, 7 out of 10 dialysis units got together in order to purchase bulk dialyzers at a cost which will be less. We changed our dialysis delivery system in order to cut the cost of dialysis. We changed the billing practices. So I want this committee to know that attempts are being made nationally to cut the cost of this very important program. Thank you.

Senator DURENBERGER. Thank you very much.

[The prepared statement follows:]

TESTIMONY OF RICHARD M. FREEMAN, M.D.

President, National Kidney Foundation

The National Kidney Foundation believes that the regulations should be withdrawn and rewritten for the following reasons:

1. The reimbursement rates appear to be based more on the need to save a specific amount of money than on any analysis of accurate cost data.
2. Dialysis units in rural areas may be under special jeopardy as are units treating primarily pediatric age patients.
3. Continuous ambulatory peritoneal dialysis (CAPD) is overemphasized as cost effective therapy superior to home hemodialysis in the absence of confirming data.
4. Inflation is largely ignored as a factor influencing reimbursement.
5. The regulations may indirectly decrease kidney transplantation.

An Evaluation of the Proposed Prospective Reimbursement Rates for Dialysis Services

(Federal Register, Vol. 47, No. 30, 6556-6582, February 12, 1982)

Proposed by the National Kidney Foundation, Inc.
2 Park Avenue
New York, New York 10016

Richard M. Freeman, M.D.
President

Comments Concerning Federal Register 47:6556-6582, Feb. 12, 1982
42 CFR Part 405. Medicare Programs: End Stage Renal Disease
Program; Prospective Reimbursement for Dialysis Services

I.	Introduction - p.6556-6558	No comment.
II.	Proposed Regulatory Provisions, p. 6558-65-61	
	C. Exceptions	We are concerned that the rural unit with relatively low utilization, that serves a population remote from a major population center, be able to achieve an exception readily and in a timely fashion. Failure of such a facility would limit access to care for the population served. We are also concerned that few if any facilities will be able to relate their excess costs due to an atypical patient mix to costs of other facilities with a similar patient mix, in view of HCFA's previously demonstrated inability to generate accurate cost data in the ESRD Program.
	G. Revision of Rate Setting Methodologies and Payment Rates	It is mandatory that the rates be adjusted annually according to a previously determined and generally accepted index of change in the cost of living. It is unacceptable to leave open the frequency and method by which such changes will be made.
	I. One Hundred Percent Cost Reimbursement for Home Dialysis Equipment, Installation, Maintenance, and Repairs	PL95-292 provided a mechanism whereby the Secretary (of HHS) could reimburse the full cost of home dialysis equipment, installation, maintenance, and repair. The proposed regulations propose to discontinue this practice by regulation, thus abolishing the statutory provision. We agree that this would simplify administration of the program and the concept of a composite rate, but we are deeply concerned with the concept of bureaucratic abrogation of a statute. Furthermore, we believe the action will be a disincentive toward increasing patients receiving home dialysis.
III.	Rate Setting for Dialysis Treatment A. General Overview	We concur with the concept of composite rates, with the concept of different rates for hospital-based and independent facilities, and with an area wage rate adjustment as prescribed by Section 2145 of PL97-35. We are aware that the political and economic reality is that there will be a reduction from present reimbursement levels as a cost saving measure as emphasized in the introduction (p. 6556), where "high and steadily rising cost of the program and the burden it can place on the Medicare trust funds..." is identified as the major problem with a program that "has been generally successful in protecting renal disease patients against catastrophic costs of medical care." It should, however, be emphasized that the rising costs are almost entirely related to increasing numbers of beneficiaries, and that there has been an actual decrease in the cost per beneficiary treated in constant dollars each year since the start of the program.

The commitment of HCFA to cost reduction is nowhere more eloquently stated than in a memo in the early fall of 1981 from Carolyne K. Davis, Administrator of HCFA, to Richard Schweiker, Secretary of HHS, in which she states: "Where to set the reimbursement rates for outpatinet maintenance dialysis depends upon the savings that must be achieved and the type of facility from whose present reimbursement the savings will be taken" (p.4, underlining by the author of this evaluation). Indeed, this statement clearly indicates that the end result is paramount, and the means by which it is achieved is secondary. The proposed regulations, and their totally, and erroneously, contrived methodology, amply support this concept.

b. Using Cost Per Treatment as the Basis for Our Rate

We concur that reimbursement should be based on the cost of efficiently and economically operating a facility. We agree that a payment per treatment session is the most obvious unit of reimbursement and approve this concept. We deplore the fact that HCFA does not have accurate or current cost data, and proposes, therefore, to establish a reimbursement level "at what appears to be an adequate level to reimburse an efficiently and economically operated facility."

C. Costs to be Included in Setting the Rate

We concur that the cost of furnishing routine ESRD laboratory services should be included in the cost per treatment calculations.

D. Costs of In-Facility Treatment

We believe the audits conducted in 1980, of 1978 and 1979 cost data, and from which costs were adjusted, should be made readily available to ESRD providers and interested organizations. We also believe the criteria by which "adjustments" were made to audited costs should be made readily available. Finally, the major identified adjustment to independent facility costs is identified as in the area of compensation to administrators and medical directors of ESRD facilities. A limit of $32,000 was "applied." We question whether this limit is reasonable, since the cost of salaries and fringe benefits for many individuals in the health care field with lesser responsibility and who supervise fewer individuals, some funded by federal funds, now clearly exceeds this compensation.

D. Costs of Home Dialysis

It is unacceptable that HCFA does not have accurate cost data on home dialysis, since all billings and payments are approved by HCFA. A survey covering only 5% of ESRD facilities with home programs is not representative, even though it covers 30% of home patients, because it includes ten of the thirteen largest programs, and is therefore biased by the largest programs, which should operate more efficiently and cost effectively by economies of scale alone. Thus, the real costs of a truly representative sample of home dialysis facilities would be underestimated by the survey, and do not accurately reflect the average cost per treatment of home dialysis as represented in the proposed regulations. Moreover, because all net growth in home dialysis is now in the rapidly growing areas of CAPD, and since CAPD may be as costly as home hemodialysis, and since CAPD supply costs are increasing at an extremely rapid rate, any survey of home dialysis facilities is of no value without knowledge of the proportion of patients on home hemodialysis vs. CAPD.

E. Rates for Independent and Hospital-Based Facilities

It is deplorable that HCFA has to "ascertain an efficient level of costs." The actual costs of both hospital-based and independent facilities for a recent reference year should be known by HCFA and then should be appropriately adjusted for inflation following the reference year.

F. Composite Rates for Home and In-Facility Dialysis

We have profound concern regarding, not the concept of a composite rate, but the factors applied in arriving at the actual reimbursement rate determined from the composite rate concept, and the potential effect of an overwhelming emphasis on home dialysis or transplantation.

First, as indicated above, we believe the cost of home dialysis has been significantly underestimated by the survey conducted. Second, "the composite rate would pay marginally less than the full cost for in-facility dialysis (1978-1979 costs) because of the home component in the facility." This would mandate that, to survive financially with the composite rate, facilities would be forced to send more patients home. We are concerned that the savings to the facility of sending patients home, having been overestimated by HCFA, will not offset the loss suffered by the facility in its in-facility operation, particularly since out-dated cost information without any adjustment for inflation was used to estimate in-facility costs.

We are also concerned that the incentive to place patients on home dialysis will lead to actual decreases in renal transplantation since, to a large extent, the same patients are home dialysis or transplant candidates. The facilities may be forced to keep potential transplant candidates on home dialysis to survive financially.

G. Adjusting Rates for Geographic Wage Differences

Although we agree with this concept, we believe that prospective, not current or even obsolete wage indices, must be used to calculate prospective reimbursement rates.

I. Summary of Proposed Methodology and Rates

The use of the median of Medicare-audited and Medicare-approved facility costs, based on 1977, 1978, and 1979 cost data (never made public) with no allowance for the 12% or greater annual inflation in the intervening 3-4 years, would result in reimbursement rates less than those costs to 46% of hospital-based and 28% of independent facilities, applying the erroneously calculated reimbursement rates of $132 per treatment for hospital-based and $128 per treatment for independent facilities. Application of the average area wage rate factor of 1.0418 to the published costs, correctly calculated, would result in an average reimbursement of only $124.58 (p.6565, $49.61 x 1.0418 + $72.90 = $124.58) for independent facilities and only $128.33 (p. 6565, $46.31 x 1.0418 + $80.09 = $128.33) for hospital-based facilities.

These corrected calculated costs would result in reimbursement of less than 1977-1978-1979 actual costs to approximately 50% of hospital-based and 31% of independent facilities. We seriously doubt that such a large percent of facilities can achieve sufficient cost reductions, even by increasing home dialysis substantially, to survive without sharply limiting quality of care, and without beginning to limit access to care. A survey of ESRD Network 8 indicates an average decrease in current reimbursement levels of 25%, with a range of decrease from 10% to 38%, and an average per-treatment decrease in reimbursement of $40. The decrease is disproportionately great for rural facilities. We are deeply concerned that some facilities will cease operation nationwide, and that a disproportionate number of rural facilities will close. This is not acceptable in a humanitarian sense or as a matter of public policy.

V. Additional Issues

A. Prospective Rates for Self-Care Dialysis Training

It is inconceivable and unacceptable that HCFA has no reliable cost data concerning self-care dialysis training, since HCFA purports to advocate home dialysis so strongly as a means of reducing costs. Facilities are now paid their approved reimbursement rate plus $20 for each training session, an amount most home training facilities find does not cover the cost of home training. The proposed regulations would maintain the $20 differential, but since the screen would be reduced substantially, Medicare would pay less per training session than now. We suggest that HCFA move promptly to address their negligence in this regard, and obtain accurate cost date for home dialysis training.

B. Prospective Reimbursement Rates for Peritoneal Dialysis and New Dialysis Techniques

We again cannot understand HCFA's lack of accurate cost data concerning peritoneal dialysis. We urge, particularly in view of the rapid growth of CAPD, which now accounts for all net growth in home dialysis in this country, and in view of the very rapidly rising costs for necessary CAPD supplies, that HCFA undertake a prompt determination of costs of peritoneal dialysis, particularly CAPD, and of pertitoneal dialysis and CAPD training.

We believe it is inappropriate for HCFA to judge CAPD a "preferred treatment for many patients." Preferred to what - to home hemodialysis - to transplantation? We are also unsure of the cost saving advantages of this form of treatment to Medicare since supplies now cost $12 per exchange, or $17,500 per patient per year, exclusive of training costs, catheter placement costs, costs of treatment of peritonitis, hospitalization costs, tubing change costs, costs of laboratory work, physician costs, etc. There is urgent need for accurate cost data for CAPD, available only to HCFA.

D. Patient Billing	Since PL97-35 still permits home dialysis patients to bill Medicare for supplies and equipment, Medicare will pay twice for home dialysis supplies in the absence of some means to reconcile facility and patient payments for home dialysis. We have no confidence that HCFA can maintain sufficient records to prevent such double payment, since HCFA's track record with regard to all other cost data is so poor.
F. Home Dialysis Aides	We seriously doubt that many facilities could afford paid home dialysis aides under the proposed reimbursement rates.
Appendix I - Regulatory Impact and Flexibility Analyis (p. 6577) Overall Effects (Col. 3)	We believe it is naive and inaccurate to state that "Since we do not expect any reduction in quality of care, the improved cost effectiveness of the dialysis delivery system would justify these changes." Of course, a reduction of 25% in average reimbursement (ESRD Network 8 Survey) will result in a reduction of quality of care, and may limit access to care, both geographically and with respect to high care patients, especially the elderly with significant other disease.

STATEMENT OF DR. JOHN NEWMANN, PRESIDENT, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, INC., NEW YORK, N.Y.

Dr. **Newmann**. Mr. Chairman, and members of the committee, thank you for the opportunity to appear here on behalf of the National Association of Patients on Hemodialysis and Transplantation, more commonly known as NAPHT. I serve as president of this association, and I am a home dialysis patient of 10 years. Also appearing with me today is our executive director, Margaret Diener.

NAPHT's membership includes over 10,000 kidney patients from every State as well as from the U.S. territories. We currently have 33 active chapters in 18 States. Kidney patients generally and NAPHT members in particular have become quite knowledgeable about their disease. The proposed changes in reimbursement policy have aroused a great deal of interest and concern in the patient community. As an association, we are committed to working with physicians and the Government for the smooth and effective administration of this program. We are not initiating, endorsing, or participating in any public anxiety-producing demonstrations. Our hopes and our rights were expressed most clearly by your press release of February 25 in which you said:

> Renal patients will not be allowed to suffer or perish because of the proposed rates. Facilities will not be allowed to exclude or reject older or seriously ill patients. And physicians will not be allowed to inappropriately place patients on home dialysis in order to take advantage of the monetary incentives provided in the new rates if those patients are not medically, socially and psychologically suited to home care.

Before addressing the specific issues of data, methodology, and impact of the proposed rule, I would like to point out that the ESRD program has been a successful one in keeping literally tens of thousands of people alive. As others have shown with HCFA data, real cost per patient per year has not increased since 1973. The program has allowed patients to continue to lead productive lives. Kidney patients work as physicians, lawyers, accountants, bankers, nurses, homemakers, students, secretaries, and in many other occupations. The anxiety within the patient community about the current proposal is directed toward our concern of a possible decrease in the quality of care currently available to patients and the possibility of the reestablishment of covert selection criteria for the treatment of kidney failure, resulting in constriction of service to those who require it. This possibility is contrary to Public Law 92-603 which guaranteed reimbursement for dialysis and transplant therapy. We therefore ask this committee and the administration one question: What will happen to the patients now being treated in the facilities which currently have costs higher than the reimbursement they will receive if these new rates are enacted? HCFA's own analysis states, "These rates would result in reimbursing 46 percent of all hospital-based facilities and 28 percent of all independent facilities at a rate per treatment below their current cost for in-facility dialysis." We consider this risk unacceptable. We are therefore requesting that the committee instruct the Health Care Financing Administration to withdraw or put a moratorium on this proposed rule and request them to develop a more complete and current data base, that being an issue which all of us seem to be concerned about, that is, the adequacy of the data. And with this, more accurate and current data base, redesign an appropriate reimbursement methodology.

We are conducting a survey of our leadership and have not yet completed that. However, it is very clear that through this, patients are asking for choice and greater incentives. They do not believe that these proposed changes provide that choice and incentives for them. An example of increasing choices available to patients would be to eliminate current restrictions on the number of dialysis facilities and the number of dialysis stations within facilities. This would encourage a much more effective opportunity for a free market to provide dialysis treatments. Per treatment costs have been contained by the reimbursement rate. The limiting of dialysis facilities and stations limit the patient's choice. Patients should be able to choose their doctors's mode of treatment and facility, because of their reputations of good care, not because they are the only ones in town.

Recognizing the need to contain costs in the program, we also recognize the very real possibility that lower reimbursement rates may result in fewer or inadequate services. Currently, there are problems with quality of care. A better method for insuring quality of care must be developed before drastic cost-cutting measures are implemented or patients will suffer. For example, in the proposed regulations, the assumption is that no data are required to determine the outcome of patients being treated for this disease. Decisions are being made on cost effects alone. What is drastically needed are outcome data as far as the medical and rehabilitation status of kidney patients. This is easily collected, but has not entered into this decision process. And we offer suggestions of this in our testimony.

NAPHT supports the composite rate as an incentive to promote home dialysis where it is appropriate. There are three serious concerns among patients: One, home dialysis is not forced on patients who are not suitable for it; two, excessive profits are not made on the free labor of home patients; and three, the service requirements for home dialysis included in the target rate program should be required for the composite rate. We specifically include the provision that a paid aide, where necessary, should be provided.

There are also issues concerning methodology. First is the assumption that inflation is not a factor. While technological changes have offset inflation in the past, we see no basis for assuming that such cost savings will be possible in the future. It is a gamble in which patients will be the losers, and we don't like gambling with our lives while the Government may be gambling with dollars.

Finally, we recognize that some changes in the delivery system are inevitable. However, they must occur without disruption in supply. Patients simply cannot discontinue treatments while the system adjusts. We fail to see how any major changes can be implemented on the day that they are announced. There are legitimate reasons for facilities to receive a higher rate of reimbursement than the norm. Requesting an exception takes time. Developing new management systems to increase efficiency takes time. Developing a home program takes time, and home training programs take time. Any change must therefore be implemented over time.

In summary, may I just mention that the data on which these rates have been developed must include inflationary considerations and quality issues. Hospital-based facilities must be maintained; however, we recognize that some hospitals may be reimbursed for excessive costs. And, therefore, we recommend that the high cost facilities be audited to establish reasonable reimbursement rates.

I would be happy to answer any questions.

Senator DURENBERGER. Thank you. We will make your full statement a part of the record in case we missed anything.

[The prepared statement, questions, and answers, follow:]

STATEMENT BY JOHN NEWMANN, PH. D., M.P.H., PRESIDENT, NATIONAL ASSOCIATION OF PATIENTS ON HEMODIALYSIS AND TRANSPLANTATION, INC.

Mr. Chairman and Members of the Committee, I wish to thank you for the opportunity to appear here today on behalf of the National Association of Patients on Hemodialysis and Transplantation, more commonly known as NAPHT. I servce as President of this Association, and I am a home dialysis consumer of ten years. Also appearing with me today is the Executive Director of the Association, Margaret Diener.

NAPHT's membership includes over 10,000 kidney patients from every state as well as from the U.S. territories. We currently have 33 active chapters in 18 states. Kidney patients generally and NAPHT members in particular have become quite knowledgeable about their disease.

The proposed changes in reimbursement policy for dialysis treatments outlined in the Federal Register on February 12, 1982, have aroused a great deal of interest and concern in the patient community. In order to understand the specific concerns of our members, NAPHT has undertaken a survey of the leadership of our organization. A brief summary of the Proposed Rule was circulated to the leaders of all our chapters, to our national Board of Directors, and to individual patients who had requested information about this proposal. Included with this summary was a survey form asking for the opinions and comments of those individuals. Over 200 of these questionnaires have been distributed.

Because this hearing is being held before we have had time to tabulate the results of this survey. I ask that this Committee allow us to provide it with additional information within the next two weeks.

The overriding concern of the Association remains the same as it has been for many years. We want to be sure that every person requiring treatment for kidney failure has access to high quality care. Since 1973 and the initiation of the Medicare coverage for kidney failure, this goal has been generally met.

Before addressing the specific issues of data, methodology, and impact of the Proposed Rule, I would like to point out that the ESRD Program has been an extraordinarily successful one in keeping literally tens of thousands of people alive and in allowing them to continue to lead productive lives. Kidney patients work as physicians, lawyers, accountants, nurses, homemakers, students, secretaries, bankers, and in many other occupations. As noted in Richard Rettig's study, "Implementing the End-Stage Renal Disease Program of Medicare," this program has had a high degree of cost containment. The cost per patient, in real dollars, has actually decreased since 1973. This has not generally been true of other medical programs.

The current proposal has created a great deal of anxiety in the patient community. As an Association, we are deeply concerned that the result of these proposals will be to decrease the quality of care currently available to patients and to cause the re-establishment of selection criteria for the treatment of kidney failure, resulting in constriction of service to those who require it. In more simple terms, this implies the real possibility that persons whose lives could be saved will not be treated and will therefore die. We view such a possibility with the greatest alarm and see it as contrary to Public Law 92-603, which guaranteed reimbursement for dialysis and transplant therapy for all those eligible through the Social Security Act.

We will be addressing some of the specific issues in the proposals later in our testimony. However, we ask this Committee and this Administration one question: What will happen to the patients now being treated in the facilities which currently have costs higher than the reimbursement they will receive if these new rates are enacted? According to HCFA's own analysis, "These rates would result in reimbursing 46 percent of all hospital-based facilities and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis."

THIS RISK IS UNACCEPTABLE. We therefore request that this Committee instruct the Health Care Financing Administration to withdraw this Proposed Rule, develop a more complete data base, and redesign a reimbursement methodology. We further suggest that this Committee consider several legislative changes at the same time.

PATIENT CHOICE

Even though our survey has not been completed, one message has become very clear. PATIENTS WANT CHOICE AND INCENTIVES. They do not believe that these changes will provide that for them. Examples of providing greater incentives to patients include:

1. sharing the savings of home dialysis between centers and patients.
2. providing paid aides for home dialysis for those who do not have suitable family members as partners.
3. waiving the 20% coinsurance responsibility for home patients who do not have other third-party insurance.
4. authorizing reimbursement for electrical costs incurred in home dialysis.

An example of increasing choices available to patients would be to eliminate current restrictions on the number of dialysis facilities and the number of dialysis stations within facilities. Per treatment costs have been contained by the reimbursement rates. The limiting of dialysis facilities and stations limits patient choice. Patients should be able to choose their doctors, mode of treatment and facility because of their reputations, not because they are the only ones in town.

QUALITY OF CARE

Recognizing the need to contain costs in the ESRD program, NAPHT also recognizes the very real possiblity that lower reimbursement rates may result in fewer or inadequate services. Currently we cannot answer the questions (after 10 years of federally funded dialysis therapy):

1. Which comprehensive dialysis programs do a better job of dialyzing and rehabilitating patients of different age groups and diagnoses?
2. Of those facilities which have commendable results, how much does it cost?
3. Conversely, what is the state of health and rehabilitation of patients treated in the lowest cost programs?

To contain costs and insure high quality care, this information is required. There are a number of ways in which this information can be accumulated and used. Examples include:

1. Hold a consensus conference to develop a mechanism to assure quality of care. This would establish what medical, rehabilitation, and cost data are needed to monitor responsibly the quality and cost of this program. In testimony before this Committee on September 28, 1981, our Association recommended such a consensus conference as a means for developing outcome morbidity data for comparative measures of quality of care.
2. Develop a dialysis facility review service, similar to the Joint Commission on the Accreditation of Hospitals. Medical reimbursement could be conditional upon meeting medical and rehabilitation standards. Quality of care and outcome standards could be developed by a joint task force of physicians and patients selected from the NAPHT, the National Kidney Foundation, and the Renal Physicians Association. Preliminary discussions have been held with members of all three organizations, and there is interest in pursuing these discussions.
3. Develop a similar accreditation and review process implemented by the ESRD Networks.

These suggestions should not be confused with "regulating medical care of doctors." Rather they act in the interests of doctors and patients by insuring quality of care and outcome and serve as a renewable licensing mechanism comparable to the JCAH.

ACCOUNTABILITY

NAPHT is concerned about the costs of the ESRD Program and was therefore disturbed to learn from the Inspector General's office that double billing and billing for "no shows" has been occurring. Further, we are concerned to learn that audits have not been done on facilities requesting exceptions. Better procedures are needed to control these nonproductive costs, and we would recommend consideration of fewer intermediaries and more audits.

We will now address the topics of data, methodology, the composite nature of the new rate, and its potential impact.

DATA

First, we do not believe that the data on which these rates are based are sufficient. There is no consideration of the quality of care currently being provided. Cost audits were apparently conducted without any consideration of the care provided by facilities. Although we cannot give a definition of quality of care, we know poor quality when we see it. Inadequate staff to deal with emergencies in a dialysis facility, staff which has had minimal training, high staff turnover, and lack of support services for patients are all indicators of problems with quality care. They are also all items which lower costs. Low cost facilities with inadequate care should be excluded from the data base.

There was a second problem with the data. Home dialysis costs were based on audits of the largest home programs. This builds in a bias which is ignored in the methodology.

METHODOLOGY

There are also several issues of concern in the methodology. First is simply the assumption that inflation is not a factor in dialysis. Data was collected for 1977, 1978, and 1979. This is 1982 and the prospective rates will be applied in 1983. While technological changes have offset inflation in the past, we see no basis for assuming that such cost savings will be possible in the future. It is a gamble in which patients will be the losers, and we don't like gambling with our lives while the government is gambling with dollars.

Another issue of concern to us is the differential impact on hospitals over indpendent facilities. Each location of dialysis has its merits but all are interdependent. A home program cannot survive without the back-up of a dialysis center. Independent facilities cannot survive without the support of hospital-based units.

COMPOSITE

This proposal intends to promote home dialysis by creating an incentive for facilities to place people at home by establishing a composite rate. Somewhat to our surprise, this concept has created a great deal of resentment among patients, particularly current home patients. Home patients often are very strong advocates for home dialysis as the preferred method of treatment. However, they are very aware that the government has paid less for their treatment for a number of years because families are not reimbursed for their labor. Now they see a proposal to provide incentives for facilities by allowing them to make a profit on their home patients. This is viewed as simply unfair. The majority of home patients who have responded to our survey have indicated that they will seek to continue the direct billing for equipment and supplies as is the current practice. Other home patients have stated that they would accept the composite rate in order to promote what they consider a preferable treatment.

Concern has been expressed that the composite rate has the potential for creating "windfall profits" from free labor of home patients. When the target rate program was established, the Health Care Financing Administration listed a number of service requirements for facilities choosing this option. We recommend that these service requirements should remain for the composite rate. We specifically would include the provision of a "paid aide where necessary" in this recommendation.

One issue which has caused great consternation among patients is what happens to those who are not able to dialyze at home. We continue to believe that home dialysis is an underutilized modality of treatment which offers advantages to some patients. However, it is not suitable for all patients for both medical and social reasons. It follows that some units will not be able to send more than an insignificant number of patients home. Under this Proposed Rule, those units will suffer financially and may be forced to cut the quality of their services to patients. The exception process outlined in the proposal notes that "atypical patient mix" would be grounds for requesting an exception to the rate. We specifically request that the definition of "atypical patient mix" include facilities which are unable to send patients home because of either medical or SOCIAL reasons.

Another issue which is frankly confusing is the elimination of the 100% purchase option for home dialysis equipment. This proposal seems counterproductive to the aim of increasing the percentage of patients at home. Further, it appears to exceed the authority of the Administration. We recommend that any new proposals retain this option.

IMPACT

It is obviously difficult to predict the impact of any changes in the reimbursement formula on patients. However, we see a number of negative effects resulting from this proposal. First the abrupt nature of these proposals has already caused a great deal of anxiety among patients. Implementation would cause even greater anxiety. We recognize that some changes in the delivery system are inevitable. However, they must occur without any disruption in supply. Patients simply cannot discontinue treatments while the "system" adjusts. We fail to see how any major changes can be implemented on the day that they are announced. There are legitimate reasons for facilities to receive a higher rate of reimbursement than the norm. Requesting an exception takes time. Developing new management systems to increase efficiency takes time. Developing a home training program takes time. Training patients for home dialysis takes time. Any change must therefore be implemented over time.

We are also concerned about the potential negative impact on patient rehabilitiation that may result from these proposals. The Proposed Rule assumes that rehabilitation will be improved with increased home dialysis. This may be true for some patients. However, decreases in social services, vocational and nutritional counseling, transportation services, and increased travel time to fewer large units can all decrease the overall quality of life for patients and may make it more difficult or impossible for them to work.

In summary, NAPHT reiterates its concern that the regulations will decrease the availability and quality of dialysis to those who need it. Specifically, we recommend that the following actions be considered by this Committee and by the Health Care Financing Administration:

1. The Proposed Rule be withdrawn. Age and diagnosis-specific cost and quality of care data should be gathered as a basis for rate setting.

2. A more effective quality assurance methodology must be developed which includes a significant role for patients.

3. Rates and methods giving patients independent choices and providing incentives to patients as well as to physicians and facilities must be considered.

4. Any new reimbursement method should be implemented gradually to prevent disruption in delivery of service.

5. If the basic nature of the new reimbursement rate is retained:

a. The methodology should be changed to offer comparable protection to hospitals.

b. Current service requirements of the target rate program should be retained.

c. The 100% purchase option for home equipment should be retained.

d. The "atypical patient mix" basis for a rate should include facilities which can send few patients home for social as well as medical reasons.

The National Association of Patients on Hemodialysis and Transplantation stands ready to offer this Committee any further help in its effort to assure that all who require treatment for kidney failure receive it. I would be happy to answer any questions.

QUESTIONS SUBMITTED TO DR. JOHN NEWMANN AND HIS RESPONSES THERETO

Question. Can you provide for the record a summary of the complaints your organization received from patients during the last 6 months. It would be helpful if you categorize the complaints by type of facility and subject. Can you tell us how these complaints were resolved?

Answer. NAPHT has had a fair amount of experience with complaints. Whenever possible, we urge people to handle complaints through the ESRD Networks or through our local chapters. It is most effective and least threatening to patients to resolve problems informally wherever possible. However, this means that we do not have statistics on complaints.

Nevertheless, we can provide some information. There have been some complaints about the quality of care in a general sense, i.e., patients who believe that the care they are receiving is not as good as it should be. More specifically, we have had a number of questions and compliants about the reuse of dialyzers. Patients want to know what they can do if they do not want to be treated with reprocessed dialyzers or if they do not feel well with this procedure. We have other complaints about patients being unable to go home, either because of lack of training facilities or because they need a "paid aide" in order to dialyze at home. We have also had questions from individuals wondering why they have been on transplant waiting lists for so long.

We handle these kinds of questions in part by referring them to our Medical Advisory Board, by encouraging patients to talk to other patients in their areas and by encouraging them to utilize local social workers or other professionals.

Because we prefer the local approach, we do not have statistics about these complaints. We are trying to develop a more formal mechanism to handle problems and should have some statistics in the future. At this time, we do know that there are complaints from both independent and hospital-based facilities, but we do not know the relative frequency by facility type.

Question. Has your association identified any facilities which provide inadequate care so that they can be excluded not only for the data base, as you mentioned in your statement, but from the program?

Answer. As explained above, we have tried to deal with problems and complaints at the local level and as informally as possible. Patients are often quite fearful of being identified with a complaint because they fear that their physicians or facilities might refuse to treat them. It has therefore been difficult to get documentation of specific complaints of the type we would consider necessary to recommend that facilities be excluded from the program.

Question. Your statement mentions waiving the 20 percent coinsurance responsibility for home patients who do not have third-party insurance. Is there a similar concern for in-facility patients? If not, why?

Answer. Our statement about waiving the 20 percent coinsurance responsibility for patients without other third-party insurance was specifically referring to incentives for patients to go home. This would be an important incentive because many patients find their non-reimburseable expenses, such as water and electrical costs, increase with home dialysis. Patients without coinsurance have therefore rarely gone home.

As far as we can determine, the general practice has been for facilities not to be very vigorous in collecting the 20 percent from in-center patients without third-party coverage. (Suppliers, by contrast, have not been as forgiving.) We are concerned that the co-insurance might be much more of a problem under the new, lower rates than it has been in the past. One likely consequence of increased pressure to pay the 20 percent out-of-pocket will be a decreased willingness by patients receiving disability insurance to return to work because of the loss of the coinsurance provided by many states. This would increase total government expenditures, although not necessarily program expenditures. I trust that this information has been helpful. I would prefer to provide more quantitative data, but that is currently beyond our limited resources. Please do not hesitate to let me know if I can be of further assistance.

STATEMENT OF NANCY SHARP, R.N., PRESIDENT, AMERICAN ASSOCIATION OF NEPHROLOGY NURSES AND TECHNICIANS, PITMAN, N.J.

Ms. **Sharp.** Thank you. Mr. Chairman and members of the committee, I am accompanied today by Julianne Mattimore and Kathleen Smith, who are cochairpersons of our government relations committee. Our association represents 3,500 registered professional nurses, licensed practical nurses and dialysis technicians. We have submitted written testimony for the record, but for our remarks this morning we would like to read from a letter which is exemplary of many we have received on the proposed regulations from nephrology nurses across the Nation. This letter was written by a nurse administrator of a hospital-based dialysis program located in a suburb of Philadelphia. The letter reads:

> I am in agreement with the proposed regulations for dialysis reimbursement as put forth in the Federal Register of February 12, 1982. I am concerned that these proposals are being seriously misinterpreted by many kidney patients and providers of dialysis care. These regulations offer the opportunity for professional nurses to enhance their role as co-providers of end stage renal disease care and to enhance patient care at a reduced cost.

The letter continues:

> I am an administrator renal nurse specialist for a suburban home training peritoneal dialysis unit. The emphasis of our program has not always been home care. Until early 1980, the majority of our patients were being dialyzed in center. At that time, we decided to take a very close look at the patients we were dialyzing and at the nursing staff. We felt that many of our patients dialyzing in a center would do better at home. In order to provide a high quality education program and professional follow up, it was necessary to hire two additional professional nurses. After these nurses were oriented, we began a full-scale home training program. We were primarily training our patients for a continuous ambulatory peritoneal dialysis. The professional nurse was responsible for the two-week training of her primary patient and the home follow up afterwards. Since that time, we have not only sent home suburban patients, but innercity and rural patients as well. Some of our patients are illiterate, some are blind, and some are paralyzed. Some patients have other organ system diseases that would have been thought contraindications to home CAPD or home hemodialysis. With an intensive professional education program and follow up, we have been able to send 23 patients home. The patients report they feel better on dialysis at home and are far happier than coming to a center. In the two

years that we have been pursuing our home training program, we have never had one patient ask to come back to center dialysis, either hemo or peritoneal.

The following case examples illustrate how patients not considered primary home candidates were trained by professional nurses and are functioning well in the home setting. (1) F.B., a 38 year old white male, has multiple organ system disease and has been on CAPD for two years. He has not had peritonitis or any other problem associated with his dialysis, although he is a diabetic, he is blind, he is unable to walk, and has lost the use of his arms to the extent that he cannot feed himself. His wife and mother do the procedure for him. They live in a trailer in Wilkes Barre. Their environment, the distance they travel to the unit on a monthly basis, and the fact that his wife and mother must do the procedure do not outweigh the benefits of having this patient at home with his family. The patient feels much better and is maintaining far better chemistries on CAPD than on hemodialysis or IPD.

(2) J.D. is a 32 year old white female. She is a diabetic and has been on CAPD for two years. She has only had one case of peritonitis, feels well, and is unrestricted in her activities. She lives in a rural community of Nottingham with her husband.

(3) W.M., a 67 year old black male, lives in an underprivileged section of the suburbs. He has been maintaining himself on CAPD for approximately nine months. This man does not read or write, but he is able to perform the procedure without problems.

I feel that the trend toward home dialysis is an opportunity for nurses to be the forerunner of change in ESRD care. It is nurses who do the training of patients for home dialysis. It is nurses who do the home follow up of patients at home. It is nurses who do the assessments of patients on home dialysis, which include physical assessments as well as noting their adaptation to a chronic illness.

Physicians and administrators associated with ESRD care are making the assumption that the quality of their patients care is going to decrease with the proposed regulations. It will be difficult to provide the same quality of care and the same type of dialysis at the new reimbursement rates. Comments are made that in order to function under a reduced rate, the professional nursing staff will have to be decreased and the technical staff increased. We should not be looking at these proposed regulations in light of how to do the same thing for a reduced cost, but rather, we should be looking at them in light of how to provide a new and different type dialysis for a reduced cost. It is how to provide this new and different type dialysis service while maintaining quality care that requires extensive professional nursing action and involvement.

This letter is a prime example of how nurses can positively influence and maintain the stability in the chronically ill patients, can establish home training programs, and can change the direction of an existing program. Our association supports such flexibility and adaptation to different philosophies of care.

We thank you for this opportunity to express our views today.

Senator Durenberger. Thank you very much for your testimony.

[The prepared statement follows:]

STATEMENT BY THE AMERICAN ASSOCIATION OF NURSES AND TECHNICIANS

SUMMARY

The major concern of the American Association of Nephrology Nurses and Technicians is Quality of Care. Addressed in this testimony are:

- o Adequacy of Data and Methodology

  We join with many others in expressing concern about the completeness and accuracy of the data on which the rates are based. However, because of the need for immediate cost containment we do not suggest delay in implementation.

- o Ability of Providers to Adapt

  Four broad areas are discussed:

  1. Dialyzer reuse -- need for strict guidelines
  2. Alteration in Labor Component -- concern about reduction of professional delivery of ESRD Care.
  3. Home Training -- the expectation for increase.
  4. Access -- concern about decreased patient access.

- o Potential effect of new rates on:

  1. Facilities -- provision for reuse and home training.
  2. Physicians -- little effect on physician practice.
  3. Patients -- perhaps more comprehensive care
     - pressure to dialyze at home
     - hardship of travel.

Mr. Chairman, members of the subcommittee:

The American Association of Nephrology Nurses and Technicians is pleased to have the opportunity to come before you to address the issues that are of mutual concern to our organization and this Committee concerning the End Stage Renal Disease Program.

INTRODUCTION

Since our last testimony before this Committee our organization has conducted three surveys of our membership on the issues before this Committee. The respondents represented all levels of ESRD care personnel and many years experience in the field. Our testimony, in large part, reflects the results of these surveys. In addition members of the Government Relations Committee of AANNT have engaged in an extensive literature search for relevant data which has aided us in formulating our views.

We shall address only briefly the adequacy of the data on which the administration based the new rates, and the adequacy of the rate setting methodology. The bulk of our testimony concerning the ability of providers to adapt to the new rates and the potential effect the new rates will have on patients, physicians and facilities is presented from our perspective of enhancing and assuring quality of care which is our major concern.

ADEQUACY OF DATA AND METHODOLOGY

We join with many others in expressing concern about the completeness and accuracy of the data on which the rates were based, and therefore, its adequacy. Of specific concern is:

- Failure to include the cost-savings effect of dialyzer reuse.[1]
- Inadequate survey of small home training unit costs.
- Lack of data on training, monitoring and support of CAPD patients and programs.
- Serious concern as to the comprehensiveness and accuracy of the data collected from the 60-day, 110 facility HCFA and IG audit as voiced by some facilities audited.

In light of these concerns about the validity of the data AANNT must question the methodologies using these data. However, because of the need for immediate cost containment in this run away program, we do not suggest delay in implementation.

ABILITY OF PROVIDERS TO ADAPT TO NEW RATES

To project the ability of the providers to adapt to the new rates is difficult. It can be speculated, however, that given the prime philosophical objective of the provider four broad areas for adaptation will be considered.

- Dialyzer reuse
- Alteration in the Labor Component
- Home Training for dialysis
- Access to facilities

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[1] "Reuse of Dialyzers," Section II Executive Summary. Office of Program Validation, pp. 18-26.

Dialyzer Reuse

There seems little question that there will be a large increase in the number of facilities employing reuse as cost-containing measure. Our organization has concerns regarding the quality control of this procedure and urges providers (in the absence of any monitoring mechanism) to establish strict guidelines regarding personnel, water purity, sterilization, storage and identification techniques.

Alteration in the Labor Component

Many, including members of our organization, have voiced the anxiety that, in light of the reduced rates, the labor component of the treatment cost will be reduced resulting in loss of social workers, dieticians and nurses. Because the survey process will be conducted infrequently, there will be little external monitoring of the professional personnel utilized by facilities. AANNT recommends that the legislation regarding social workers and dieticians be retained as it is and that the legislation regarding registered professional nurses be modified. Currently, it is required for a registered professional nurse to be responsible for nursing service in the facility, but does not require a registered professional nurse to be present during dialysis. We believe one registered professional nurse should be on duty in the facility for every six patients being treated.

Home Training

It would seem reasonable to expect that providers who do not offer home training will now find it attractive to do so. This may require alterations in legal contracts, physical environment, and staffing patterns.

Access

AANNT joins the National Association of Patients on Hemodialysis and Transplantation in expressing concern that the reduced rates will cause reduction in access to quality care. It seems reasonable to assume that the more difficult it is to make dialysis profitable, the less attractive it will be for new facilities to open; and those showing a low profit margin to remain functioning. This may result in hardships to patients -- especially in rural areas.

POTENTIAL EFFECT THE NEW RATES WILL HAVE ON PATIENTS, PHYSICIANS AND FACILITIES

The potential effects of the new rates should be widespread. We shall address how we see the potential effect on:

- Facilities
- Physicians
- Patients

Facilities

As mentioned above, facilities will have the need to make provision for reuse of dialyzers. In addition to physical changes for reuse physical changes for Home Hemodialysis Training will be necessary. Experienced End Stage Renal Disease educators should be employed to deal with this added responsibility. Similarly, provision will have to be made for training in CAPD. AANNT is preparing a two week intensive seminar for experienced dialysis nurses on:

1. Principles of Learning.
2. Methods of Teaching.
3. Evaluation Methodology.

Physicians

In general, the new rates should have little effect on physician practice. It is hoped that in the future nurses with ESRD experience will be recognized for their expertise and be the coordinators of patient care, leaving the physician free for patient problems, emergencies, monthly visits, etc.

Patients

Should nursing be recognized for its expertise in evaluating the state of "illness" or "wellness" of Chronic ESRD patients and directing them to their potential for rehabilitation, the patient may receive less fragmented more comprehensive care.

Facility Patients may feel pressure to dialyze at home and be resistant to it. Should they be physically, socially and emotionally able, with the appropriate support, they should be trained and given a trial at home with the assurance that should problems arise that are insurmountable, they may return to the facility.

In addition, as mentioned above, patients may face considerable hardship in the form of distance and transportation should some facilities close. However, no patient will be left without care.

Thank you for this opportunity to present the views of AANNT.

Senator **Durenberger**. Dr. Freeman, let me ask you who it is that is in the best position to judge the issue of quality of care in ESRD treatment?

Dr. **Freeman**. You said who makes the decision about the quality?

Senator **Durenberger**. Who is in the best position to make that judgment?

Dr. **Freeman**. In terms of an individual patient who has begun dialysis?

Senator **Durenberger**. Yes.

Dr. **Freeman**. I think it is a combination of individuals: the doctors, the nurses are critical, the social workers, anyone who has contact with that patient, evaluates the quality of care for that patient. So it is not a single individual who is making that decision. And, in fact, those decisions are seldom made. Our point is to try to keep the person alive. We were meant to keep people alive, not to make them productive, although that is important. But that is not the main aim.

Senator **Durenberger**. Dr. Newmann, let me ask you the same question. I recall from our first hearing on this subject that, at least initially, quality is difficult for the patient to judge.

Dr. **Newmann**. Well, certainly I agree that the patient, medical staff, and doctors are in the best position to make that judgment. Our concern is in terms of quality of care, in setting these new reimbursement rates. We point to audits which may show the least cost facilities, and perhaps facilities which generate higher surpluses, although there is no look at what has happened to the patient population in a low cost facility. Our association does receive complaints of treatment and are wondering whether they are getting the best care. We are not suggesting that the Government become the determiner of quality of care; however, we do feel—and I believe many physicians would agree—that it would be very helpful to have baseline outcome data on what is happening to patients so that those units which may not be doing a job comparable to the norm should be investigated.

Senator **Durenberger**. Is there a point at which you can directly relate the quality to cost?

Dr. **Newmann**. The only way in which I think you can relate quality to cost for a complete unit would be to have outcome and rehabilitation status data by age group and diagnosis, and look at what the norms suggest. Then if you have a unit, for example, whose mortality rate lies, in statistical terms, two standard deviations outside the norm, you would want to investigate that unit. Currently, nothing is being done in this regard. That would certainly deal with cost and quality.

Senator **Durenberger**. If we are trying to use prospective payment as a mechanism to stimulate efficiency, choice, and more competition among providers, then the patient—or consumer—obviously becomes an important part of this process. I suggested earlier, that it might be possible to move this reimbursement system in the direction of the consumer rather than segregating it by provider. Do you feel the payments to providers could flow through patients?

Dr. **Newmann**. Yes. I definitely do, and I think our association definitely supports more consumer choice. We believe that one of the first things that should be considered would be to do awav with the certificate of need requirements. If this was the case, there is a possibility that you would have increasing numbers of facilities available. This would not reduce cost containment because the cost is contained with the reimbursement rate. But as it is now, certificate of need has resulted in limiting facilities so that a patient may only have a choice of one or two facilities in an area. And certificate of need has resulted in most of those facilities being filled. So even if there are others in the same town, he may not be able to get treated.

Senator **Durenberger**. Is that what you were referring to earlier when you talked about the existing limit on facilities and stations?

Dr. **Newmann**. That is correct.

Senator **Durenberger**. Is the HSA's certificate of need process accomplishing that?

Dr. **Newmann**. It is redundant.

Senator **Durenberger**. Well, health planning may be replaced by something else, but you can count on planning in its present form being out the window.

Dr. **Newmann**. Excuse me. Ms. Diener.

Ms. **Diener**. I would also like to point out that patients are very interested in financial incentives for them for home treatment. They read these regulations and they see incentives for everybody else. They would like to talk about some kind of cost sharing, or profit sharing if there is a savings. They would like to talk about waiver of 20 percent coinsurance or subsidy of electrical cost, or some of those kinds of things.

Senator **Durenberger**. I appreciate hearing that. Thank you. Senator Dole?

Senator **Dole**. Well, I had asked that question earlier of one of the witnesses, about what real incentives are there for the patient. Obviously, there are some incentives: He wants to stay alive. I think that ought to be fairly high on the list. But in addition to that, there may be other areas that we could properly address that that would provide an incentive to lower the cost of the program. I don't think anybody objects to lowering the cost of the program.

Dr. **Newmann**. No.

Senator **Dole**. And one way to lower the cost of the program is take some of the fat out of the provider end of it. You don't have any objection to that, do you?

Dr. **Newmann**. No. In our survey, we did get comments from patients who, in a sense, resented the possibility of the new reimbursement rates resulting in greater profits for the facility because in the past their cost to the Government have been lower, being on home dialysis. Perhaps a reasonable compromise here would be, as it was suggested, to share these savings with patients, I think, which would be an attractive incentive.

Senator **Dole**. And certainly those in the private sector are entitled to make a profit. I don't suggest that they shouldn't make a profit.

Dr. **Newmann**. Absolutely.

Senator **Dole**. And we are concerned, I think, as Dr. Freeman may have indicated, in rural areas. But in my State there are only four; they are all hospital-based. Are you concerned that the rates are so low that they might threaten the existence of those four facilities?

Dr. **Freeman**. Yes. I am from Iowa, and we have a similar problem there.

Senator **Dole**. Do you have any free-standing clinics in Iowa?

Dr. **Freeman**. Well, all of our dialysis units are also hospital-based. And there is a concern that the cost reimbursement, because of the wage factor, may be low. We have problems getting nurses in rural areas because of the competition. And there is some concern there that those units may be constricted. And there are only 10 throughout the State.

Senator **Dole**. But isn't there always a concern when those of us who have responsibilities to take a look at the budget and where we can save dollars without impacting on patient care? There is always a concern, and it should be for those of you who provide it and those who receive it. We don't want to go so far that we adversely impact on quality care.

Dr. **Freeman**. That is precisely it.

Senator **Dole** So that is not the purpose of this committee. I don't have dialysis, but I only have one kidney, and I had a stone in that last year. So I have a little interest in kidneys. So we don't want to leave the wrong impression that somehow we are looking at ways to cut the program even if it adversely affects the patient. But there is a lot of fat in this program. I don't think anybody could stand here, even under oath, and say there is not a lot of fat in the program.

Dr. **Freeman**. We want to just make sure that the fat is removed, and not the heart and the liver and the kidneys.

Dr. **Newmann**. Our suggestion of auditing the high cost facilities, whether independent or hospital, I think, which should be taken with quite a bit of seriousness. I believe in the hearings 2 weeks ago it was pointed out that all of the facilities which have received exceptions, for the most part, have never been audited. We suggest that one of your greatest cost saving procedures would be, rather than to implement these new rates which do put many units at risk, to audit the high cost facilities to establish reasonable rates there while you are getting a more reasonable data base to develop appropriate rates and methodology.

Senator **Dole**. Why not do it the other way? Why not go ahead and let the rates take effect, and then we will see what happens? Keeping in mind that we are not going to let anything happen to the patients.

Dr. **Newmann**. Well, if you did that, we would be very concerned as to what would happen with HCFA's estimate of 46 percent of the hospitals which will be at risk and 28 percent of the independent units. We don't know how to answer that risk question.

Senator **Dole**. But can we keep postponing any reform in the program, and I realize that a lot of that cost is inflation, there are more patients, but I think the nurses are doing the best they can to encourage home dialysis. Is that the thrust of your statement, that it is effective, and it can be done by most anyone. We are not trying to push home dialysis off on patients who need additional care, but if we can get dialysis for $97, plus the other advantages that come with home dialysis, the fact of the setting and everything else, it would seem to me that we ought to be looking for ways to give the incentive to the person who does the dialysis, the patient, rather than—again, understanding that we are not going to cover every patient. What would be the most you think you might ever reach anyway, 50 percent?

Dr. **Freeman**. I think 50 percent now would be maximal.

Senator **Dole**. Seventeen, as I understand it now.

Dr. **Freeman**. That is right, it runs from around 11 to 17. But that has been largely related to peritoneal dialysis rather than home hemodialysis, which has been almost stable.

Dr. **Newmann**. I wouldn't get locked into a notion of 50 percent, as I believe is the case. All new patients going on dialysis for the last few years, their average ages have been 50 to 55, and many of them have been entering with other complicating diseases, mainly, cardiovascular and diabetes, which was not the case when people, like myself, were selected for the program 10 or 11 years ago, who primarily had simply kidney failure. So it is true that we may run into trouble there.

Senator **Dole**. Well, I agree with that. I don't mean to suggest that as a goal. But I would just say, finally, that we want to assure those of you concerned about patients, as well as providers, that no one is trying to destroy the program. That is not the purpose. But there are areas, whether it is machine rental or whether it is something else, where we ought to be taking a look at the cost. After all, we are the, supposedly, the board of directors for the American taxpayer. But I don't think so far that we have met if you look at the cost of the program. So we shouldn't get any directors' fees for the past couple of years in this program. [Laughter.]

Senator **Durenberger**. Thank you. Senator Baucus?

Senator **Baucus**. Thank you, Mr. Chairman. To follow up on that last question—you are experts in this area—you have heard the GAO testimony. To what degree do you agree with their conclusions about waste in the program, and, second, according to your personal experience, where is the fat? Where is the waste?

Dr. **Newmann**. I will speak personally here. I think there is no doubt that there are many hospitals around the country who have received exceptions which are much greater than need be the case. I think it is quite possible that the independent units can be receiving greater surpluses than what one would consider reasonable profit, reasonable profit being what the cost of capital is. And, whereas, some of the nonprofit organizations, facilities, may use these extra surpluses for additional amenities for patients' research. Up in Seattle, they use it for paying home aides in areas where you don't have a suitable partner. In a for-profit center, they are clearly responsible to their shareholders. So an extra dollar earned there may not necessarily go into patient rehabilitation. We are not against reasonable profits. It is the question if there are excessive profits there.

Senator **Baucus**. Does anybody else have a view?

Ms. **Diener**. I would like to respond to the question about the GAO audits because although we have not seen the data, we are concerned that there was no analysis of the quality of services rendered in facilities that were audited. And we get a fair number of complaints now from patients who feel that there is inadequate staff, improperly trained staff, lack of support services: rehabilitation, vocational, nutritional.

Senator **Baucus**. Would that be hospitals or would that be with the free standings?

Ms. **Diener**. We get it from all types of facilities. But we think that any audit data has to look at whether the services provided are adequate. We realize that money does not guarantee quality, but the absence of it may very well guarantee the lack of quality.

Senator **Baucus**. My question only goes to waste. Where is the waste? I understand there are probably legitimate patient complaints, and I appreciate that very much, and that is very high on our list of priorities, but I am just trying to figure out where is the waste right now. You are involved in this program.

Ms. **Sharp**. Right. OK. Our organization agrees that there needs to be more data, and that the methodology is questionable and all of that. OK? But that does not preclude the idea that we have got to go on with this program. By, first of all, giving the patient education into what his choices are. The patient must be educated into choices; that must come first.

Senator **Baucus**. Physicians aren't doing that?

Ms. **Sharp**. Not to the extent that they should be. And in network 23, they are doing a study that is on a form, "Patient Consent," and they can describe what is happening right here in this Washington, D.C., area. No, they are not doing that to the extent that they should be. The patients need more education, even to the choices. But even those patients who are in center, who have chosen or will choose to stay in center, there are things that they ought to be educated about in the disease process and in self-care measures that would reduce the extent of complications which the patient ends up in the hospital for. There are simple basic educational things that the patient should know so that even they reduce the rate of complication, and that will reduce waste in keeping the cost of hospitalization down. And it is not hard to do.

Dr. **Freeman**. Maybe I should respond to your question. One can have a Cadillac program or a Chevrolet program. In the State of Iowa, until recently we had a Cadillac home hemodialysis program. As part of the concerns about the constraints, we now have a Chevrolet home program. Not an Omega. And we realize the costs were too high, so we are using a less expensive dialysis delivery system than we did before. Our dialyzers are less expensive than before. We got together as a group to increase the volume in order to cut the cost. Those are potential wastes in the program.

Senator **Baucus**. Why did Iowa do that? What were the incentives for Iowa to do that?

Dr. **Freeman**. Well, because I thought you were going to do it. [Laughter.]

And now I am worried, you see, because our costs are down. I am worried that something is going to come along and base something on cost and we are going to be in jeopardy because we have voluntarily cut our cost already. No. But it was part of a national impact to try to cut the cost of dialysis. We are very much concerned about that.

Senator **Baucus**. And other States can do the same.

Dr. **Freeman**. I suspect that most of us could cut down some, but I am not sure if that is 4 percent, 5 percent. I am not sure what is safe for our patients. And that is what we are concerned about.

Senator **Baucus**. All right. I have 30 seconds left, Mr. Chairman. One quick question and one quick answer. What is the future of greater kidney transplants?

Dr. **Freeman**. Kidney transplants have been largely stabilized. Cyclosporen has helped in a small way, but it has been largely stabilized. And the age of our kidney population means that it is not likely to increase.

Senator **Baucus**. You don't think there is much of a future?

Dr. **Freeman**. Well, no, I think there is if a medical breakthrough comes through. There is always that possibility.

Senator **Durenberger**. Thank you all very much. We appreciate it.

[Questions submitted by the chairman and responses thereto:]

QUESTIONS SUBMITTED BY THE CHAIRMAN AND ANSWERS THERETO

Question. Hospital-based facilities are more expensive in terms of labor, supplies, and overhead. In your opinion, is there any justification for those higher costs?

Answer. Hospital based facilities are more expensive than free-standing units. This is due, in part, because the program has evolved in this manner. More important, however, is the reality that there is a spectrum of care that must be available for optimum treatment of indivuduals with kidney failure. Very stable patients can be cared for in "low cost" free-standing facilities, but there must be access to a higher level of care at all times. Many patients require more intensive monitoring of the dialysis procedure and interdialytic care. Examples of the latter are diabetics, hypertensives and those that have unstable dialysis procedures.

Hospitals must always be prepared to receive emergencies: new cases close to a terminal state, referrals from other centers of patients with complications or acute illnesses not related to renal failure and individuals that require a spectrum of facilities not available to free-standing units. Thus, hospitals must maintain "open slots" for referral of such patients from free-standing units or home care. Hospitals must maintain equipment, ancillary services and a higher personnel to patient ratio compared to units that care for stable patients. The link in the chain of accessibility to higher levels of care must be maintained. Similarly, as patients stabilize they can be transferred to other "low cost" units. Hospitals that support a transplant program require dialysis support while the patient is being evaluated for transplantation and to treat the patient following surgery if there is failure of kidney function following surgery or during an acute rejection episode. It would be very difficult to maintain a transplant program without and adequate sophisticated dialysis unit.

There is no argument that large hospital based units that treat stable patients can operate in a manner similar to free-standing units and probably should be phased out over a period of time except in circumstances addressed under atypical patient mix, question 4.

Question. In a recent letter to the Secretary, you stated that the alternative reimbursement method is reflective of a range of services such as on-call availability; renal dietetic management; laboratory, psycho-social, medical and transplantation evaluations; patient care conferences; and others. Are some of those services provided by nurses, technicians, dieticians, social workers, and physicians hired by the facilities and paid out of facility reimbursements? If so, isn't the proposed physician reimbursement scheme inequitable?

Answer. The alternate reimbursement method was derived to compensate physicians for a broad range of services and other activities. The physician has the ultimate responsibility of the care of each patient and the management of the entire program. He/she prescribes the appropriate treatment for each patient then delegates portions of that prescription to other members of the health care team. Each member of the team delivers their segment of the prescription but no member of the team has the total responsibility for the care of individual patients or for the medical management of the entire program. This rests solely with the physician. The physician, as leader of the team must monitor the effectiveness of each employee to ensure efficiency and quality of performance. The lay medical administrator cannot and should not participate in these assessments of quality and efficiency.

The physician is the only person capable of making a comprehensive assessment of the medical needs of the patient based on his/her assessment, range knowledge and responsibility inherent in the medical code of ethics. This cannot be delegated under present medical statues.

You are aware that the increase in the total cost of the ESRD program is not due to an increase in the cost per treatment (in real dollars) but on an increase in the numbers of patients treated. The physician carries the burden of responsibility to these pressures of an ever increasing number in the population of patients presenting for treatment. There is inequity in the reimbursement system but it is opposite from that posed in the question. This is because the case load per physican has increased over the years without a significant increase in reimbursement.

Question. Isn't it likely that physician ownership of for-profit dialysis units, and profit sharing arrangements involving hundreds of thousands of dollars, influences the medical decisions made by those physicians and therefore the care provided to patients? What is the stand of your organization on the ethics of such profit sharing and ownership arrangements?

Answer. The third question has two parts: economic influence on medical decision making and the ethics of ownership arrangements. Though there may have been instances of abuse in the system they must be very few. We are not aware that any physician or facility has been prosecuted with a decision against the physician/facility. We are adamant that the vast majority of physicians have responded to the mandate of Congress of 1972 and have rendered therapy of the highest quality to patients. This is reflected in the exponential increase in the numbers of patients receiving therapy since 1973. It is a reponse by the medical community in the United States unparalleled by that of any other country. Further, it is very difficult to abuse the ESRD system because of peer review under utilization review processes, state and federal inspections, network and society surveillances that maintain standards for optimal care. ESRD treatment programs are quite different than individual private practice or isolated actions because it is a program.

The medical community is divided on the ethics of ownership. Legally there is no precedent to deny physicians ownership since physicians own and operate nursing homes, own and operate hospitals and own and operate clinical laboratories. It is perfectly legal for physicians to have this involvement as long as the performance and operation of the programs meet federal and state codes and regulations. If it is determined that it is unethical for a renal physician to have an ownership arrangement then that ethic must be applied across the board to other medical programs. Otherwise, it is discriminatory to renal physicians.

Some physicians do not feel it is ethical to have an ownership arrangement but no specific hard reason for this view can be set forth unless a significant difference in access, efficiency and quality of care can be demonstrated in profit sharing versus non-profit units.

Question. That criteria do you believe should be used to define an atypical case mix? And based on your experience, do case-mix differences translate into higher dialysis treatment costs?

Answer. Atypical case mix needs exact definition and, again, application of these definitions must be made to derive precise data for future planning. Some instances that should be considered for atypical case mix are:

(1) A single facility services a large geographic area.

(2) A facility supports a transplant program.

(3) A hospital based facility contracts to back-up free-standing units for complicated patients and individuals with intercurrent illnesses.

(4) Centers that treat a high percentage of children.

(5) Centers that serve a larger population of individuals with psycho-social problems such as illiterate, indigent, etc.

(6) The center serves a high proportion of patients that require a higher number of admissions than stable patients.

This response is largely that of the President of this organization but is based on the policies of the Renal Physicians Organization, or where there has been no policy, the input of as many members of the Board of Directors that could be reached in the short time period available for comment. Each item could be expanded in more detail and I would be happy to do so at your request.

Senator **Durenberger**. Our next witnesses are Dr. Richard B. Freeman, president, Renal Physicians Association, Chicago, Ill., who is accompanied by Dr. John H. Sadler, legislative committee chairman, accompanied by Mr. Robert Pristave, counsel; Dr. Christopher R. Blagg, director, Northwest Kidney Center in Seattle, Wash.; Dr. Norman Deane, director, Manhattan Kidney Center; and Dr. Walter Gardiner, who is medical director of the dialysis unit at Meharry Medical School and Hospital.

STATEMENT OF DR. RICHARD B. FREEMAN, PRESIDENT, RENAL PHYSICIANS ASSOCIATION, CHICAGO, ILL.

Dr. **Freeman**. Thank you, Mr. Chairman. I am Richard B. Freeman, president of the Renal Physicians Association, head of the nephrology unit at the University of Rochester. I have been a nephrologist involved in patient care, research, and teaching for 25 years and I drive a Chevette. [Laughter.]

I am speaking on behalf of the 700 members of our organization, all of whom are involved in the direction of individual programs, and the care of patients with kidney disease throughout the United States. We appreciate this opportunity to comment on the proposed rulemakings under question. We fully appreciate the economic climate and the necessity to conserve resources. We perceive clearly tension expanding between our ability to deliver life-saving therapy at the bed side and the potential of limited resources. However, we believe that the imposition of an abrupt change in this program, based on misperceptions, faulty data analysis, and a very short period of time for study would be a very serious mistake. I would add further that two changes in a short period of time would add to the chaos and make it almost impossible to conduct a program. We believe that dialysis and transplantation are successful methods of therapy. They save the lives of thousands of Americans. We contest the statement that rehabilitation has been inadequate, and the cost of this program is excessive when compared to the cost of other social programs.

I am going to dispense with most of the written statement.

Senator **Durenberger**. Without objection, it will be made a part of the record.

Dr. **Freeman**. Thank you.

[The prepared statement and a supplement thereto follow:]

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Dated March 11, 1982

Statement of the Renal Physicians Association Responsive to the Senate Finance Subcommittee on Health's Hearings on the Department of HHS's Proposed ESRD Regulations, Dated 12, 1982

The Renal Physicians Association is in the process of preparing a detailed responsive analysis of the proposed ESRD regulations dated February 12, 1982. Because of the voluminous nature of these proposed regulations, this work is not completed yet. Thus, at this time, we submit the following as the salient points of our criticism of the proposed regulations.

-- The proposed regulations threaten to diminish entitlement benefits to ESRD patients through an unacceptable reduction in reimbursement rates to a majority of providers, such that patients may be denied access to care.

-- The Health Care Financing Administration ("HCFA") attempted to circumvent the statutory provisions of the law and failed in truly developing a dual composite rate. Accordingly, HCFA has placed an inordinately large number of hospital programs, independent facility programs, and their respective patients in jeopardy. Further, the methodology used has penalized those facilities which account for the highest percentage in home dialysis, an action completely contrary to the statutory intent.

-- The methodology and faulty cost figures used by HCFA in the establishment of these reimbursement rates were designed to arrive at predetermined rates dictated solely for program savings. This was not the specific intent of Congress, nor is it for the specific good of the patient.

-- The proposed changes in physician and facility reimbursement will be counterproductive by compounding the problem of the availability of physicians and other health care professionals to care for patients. This will increase the risk of more hospitalizations and cause a decline in the quality of care which will result in an increase in cost.

It is unrealistic to expect providers of care to adjust so abruptly to massive reductions in reimbursement without major adverse effects on patient care.

The proposed regulations must be re-evaluated and altered significantly so that the ESRD program conforms with the intent of Congress and the needs of patients are met in an orderly fashion.

SUPPLEMENTAL STATEMENT OF

RICHARD B. FREEMAN, M.D.

PRESIDENT, RENAL PHYSICIANS ASSOCIATION

In addition to its prepared statement and testimony before the Subcommittee, the Renal Physicians Association hereby appends this supplemental statement on the Medicare End-Stage Renal Disease (ESRD) program and the Notice of Proposed Rule-Making published by the Health Care Financing Administration (HCFA) regarding prospective reimbursement for dialysis services (hereinafter the "proposed rule").

The proposed rule states that it is intended to improve the administration of the ESRD program and control the "rapidly growing costs" of furnishing dialysis. HCFA has assumed that by implementing these changes, the provision of dialysis services by facilities and physicians will not be adversely affected. An analysis of the proposed rule by the Renal Physicians Association (the "Association") clearly indicates a contrary result. We would like to take this opportunity to make additional comments on the proposed rule in the following areas: (1) the audit data upon which the proposed prospective rates for dialysis services are based; (2) the deficiencies in the methodology setting the proposed prospective rates for both facility and physician reimbursement; and (3) the various assumptions which HCFA has made in formulating the proposed rule:

THE DATA BASE

In March, 1980, HCFA selected a stratified sample of 110 dialysis facilities for audit. The purpose of those audits was to provide verified cost data for facilities reimbursed under the ESRD program. The data resulting from those audits form the basis for the proposed prospective rates set forth in the proposed rule. The Association objects to the use of the data because we do not feel that it is accurate nor representative of the costs incurred by renal dialysis facilities nationwide.

To begin with, the audits conducted were limited in scope. They consisted of desk reviews of hospital-based facilities' cost information and a different but limited analysis of free-standing facilities' financial information. Audit adjustments were made by HCFA to costs reported by facilities which resulted in a reduction of costs of approximately 15% for free-standing facilities and 3% for hospital-based facilities. A reduction in the costs of that magnitude for a facility operating at the median of $108 per treatment amounts to approximately $20 per treatment. However, facilities were not given the opportunity to challenge or review the adjustments. The inability of facilities to question the adjustments makes the data suspect because the only basis for the adjustments were the unquestioned assertions of the auditors. Thus, if any errors were made either in the method of conducting an audit, the consistency thereof with other audits, or the adjustments made, no input was allowed by the facilities.

In addition, the nature of the adjustments is questionable. Various positions were taken by HCFA auditors that certain costs were not allowable either because they were specifically not allowed under Part A cost reimbursement principles or they were "out of line" with what HCFA considered to be a reasonable cost. A glaring deficiency in the audit analysis, for example, was the arbitrary limitation imposed on medical directors' compensation of $32,000 per year. This was based on the assumption that the duties and responsibilities, and therefore, the salary of a medical director of a dialysis facility were equivalent to those of an administrator of a small hospital. In fact, a medical director is required by Medicare regulations to not only have a high degree of administrative skill, but also to possess certain medical credentials and perform medical functions which certainly would place his reasonable compensation above that of an administrator.

Audit data was also gathered for home dialysis programs. That data collection effort was limited, however, to less than 5% of the ESRD home programs which included 10 of the 13 largest and most efficient programs. Because these programs can by virtue of their size take advantage of certain operational efficiencies and economies of scale unavailable to smaller programs, their costs are likely to be lower and unrepresentative of the majority of home programs. The representative nature of the costs was further diminished by the weighting of those costs on a per treatment basis. As a result, the home data was not indicative of what home dialysis costs would be for most facilities.

RATE METHODOLOGY

The rates are also based on what the Association believes to be, at least in part, a faulty methodology.

Perhaps the greatest deficiency was the failure of HCFA to adjust the data for the increase in costs over time. The audited data covered a period from 1976 through 1979. Nevertheless, HCFA relied on the raw data without adjustment for inflation in determining its prospective rates. HCFA's failure to adjust for inflation for the intervening period renders reliance on that cost data arbitrary and capricious and causes the proposed prospective rates to be suspect.

HCFA has also assumed that the cost data of all free-standing facilities and all hospital-based facilities are homogeneous and fungible in nature and that these costs can be combined to produce a median cost to be used in rate making. What HCFA fails to realize, however, is that there are state regulations with which some facilities must contend which may cause them to incur certain costs that other facilities do not. For example, the reuse of hemodialyzers, a practice which is highly cost-efficient, is constrained by state law or regulation in some circumstances (such as in California, Colorado and Alabama). Similarly, some state licensure laws require certain physical plant requirements and staffing ratios which effect the ability of the facility to reduce costs. No adjustments were made in the data for these factors.

The methodology also provides for two rates, one for free-standing facilities and one for hospital-based facilities. The same factors are considered in determining both rates except for two adjustments to the hospital-based facility rate; one for the excessive amount of overhead incurred by hospital-based facilities and an additional adjustment of 5% for shortcomings in the data and the age of the data. These factors are not taken into account for free-standing facilities, however.

While a different rate for hospital-based facilities may be a legitimate goal and consistent with Congressional intent, the bases used to distinguish between free-standing and hospital-based rates are clearly unjustifiable.

PHYSICIAN REIMBURSEMENT

In the proposed rule, HCFA proposes the concept of a monthly capitation fee which is similar to the Alternative Reimbursement Method ("ARM") currently in effect. HCFA has stated it desires to take a neutral position in reimbursing physicians in order to encourage physicians to place patients on home dialysis. The Association objects to the proposed system basically for three reasons.

First of all, the proposed system does away with the initial method of reimbursement. There is no statutory authority for this elimination. For that reason alone, the proposed rule is defective.

Secondly, HCFA has set a reimbursement rate by tying it directly to a multiplier of 12.4. The proposed rule states that since a patient receives treatment on the average of 12.4 times per month, the physician's reimbursement should be 12.4 times a brief follow-up office visit charge, plus an intermediate follow up visit charge. The rate utilizing the 12.4 multiplier is not an accurate indication of the physician services rendered to dialysis patients. The Association has taken the position since 1974 when the ARM was implemented, that a multiplier, if used, cannot be tied directly to the number of patient dialysis sessions. The physician's duties not only include the hands-on treatment of the patients during their dialysis sessions, but also include the on-call responsibilities, cognitive skills and other specific procedures which go above and beyond a simple brief office visit charge multiplied by 12.4.

Thirdly, the proposed rule continues to perpetuate the practice of HCFA to ignore the ARM with respect to the application of the cumulative economic index on an annual basis. Part B reimbursement for physician services generally applies the economic index. Its purpose is to recognize changes in expenses of physicians' office practice and general earnings level. Yet, HCFA has not adjusted the rate for the ARM since 1974 (except for a minor adjustment in July, 1978) while other physicians' reasonable charges have been consistently adjusted.

Thus, the Association submits that the proposed rule dealing with the proposed physician monthly capitation fee should be totally revised.

GENERAL COMMENTS

In general, the Association believes the proposed rule is inappropriate because it is based upon invalid assumptions. One of the primary assumptions is that the ESRD program is incurring costs in excess of the value of the services provided.

Total ESRD program costs have risen from about $228 million in 1974 to $1.5 billion in 1981, while beneficiaries have increased from 11,000 to 60,200. Since 1974, the cost per treatment per beneficiary has increased a mere 2.5% per year, while for the same period of time, the medical services component of the consumer price index has increased 96% or 12% per year. It can be seen, therefore, that the ESRD program has been cost efficient.

HCFA also assumes that physicians and/or facilities place patients on in-facility dialysis for purely economic reasons. A facility has little or no decision making power as to the mode of treatment for a patient. It is the patient's own physician and ultimately and most importantly, the patient who is the decision-maker. The patient must determine his or her own preference and abilities to deal with a particular mode of treatment, such as home dialysis, before that method of therapy is undertaken. Thus, HCFA misstates the overall ability of the facility and/or physician to control and dictate the patient's treatment mode.

The proposed rule also states that CAPD is a preferred mode of treatment for many patients. See 47 Fed. Reg. 6568 (1982). In fact, CAPD is a relatively new mode of treatment with a medical technology which is in the experimental stages of its development and continues to be evaluated. CAPD has not yet proven its medical efficacy over time. Until an adequate period of time has passed in order to develop information and statistics on mortality and morbidity of patients who are being treated for end-stage renal disease by CAPD, the Association strongly objects to HCFA's characterization that CAPD is a preferred mode of treatment.

Finally, it is important to note that in seeking to reduce costs through the proposed rule, HCFA may in fact be increasing the costs of the program in the long run. In order to make ends meet under the reduced reimbursement levels facilities may be required to reduce their costs where possible, such as in the area of labor. Reduced patient care may result in greater patient morbidity. Patients may then be more apt to be transferred to hospitals for in-patient treatment. Without question, a patient who has been admitted to a hospital as an in-patient to receive dialysis treatments is more costly to the Medicare program than are patients who are treated in an adequately staffed out-patient facility.

CONCLUSION

In conclusion, we would urge that HCFA work with the Association and provider and patient groups to develop a workable and sensible rate-making proposal as an alternative to the proposed rule once it has developed a reliable data base.

Dr. FREEMAN. We are in total agreement that the data that has been developed by HCFA on the 110 units survey is too old. It is 6 years old; it began 6 years ago. There is no basis in fact for the rates that have been established for facilities or for physician reimbursement. There has been no consideration for inflation. This has all been stated before. The Renal Physicians Association made a survey of 825 non-Federal units, which is very close to the total number of units operative. Fifty-four percent of these were hospital units and 4.7 percent of those units indicated they could not meet the proposed reimbursement rate. Forty-six percent of the units responding were freestanding units; 7.5 percent of them indicated that they could not meet the proposed rates.

The reimbursements for freestanding units and hospitals have, in our mind and in our interpretation of the regulations, ignored the Omnibus Reconciliation Budget Act of 1981. We believe that this is an affront to Congress. The rates set and established are essentially the same. There has been a 5 percent addition to the hospital rates, and we believe that this is a pro forma matter that has been made in an arbitrary manner. We heard from Dr. Davis this morning that that was indeed true.

In regard to the physician, the physician reimbursement has been exactly the same since 1973, except for a $1 increase per treatment in 1978. It is now proposed that that reimbursement be reduced by one-third. It is proposed in an attempt to increase home dialysis. These are a number of statements, but I would like to point out several other items in the limited time that I have. One is that there apparently is no appreciation of the fact that a dialysis unit in a hospital serves as a focal point for many other extra corporeal therapies, like hemoperfusion, cancer chemotherapy, plasmapheresis. It is the focal point, and is necessary, for a successful transplant program. Specifically dialysis is required to prepare the patient for a transplant, to sustain the patient if the transplant fails to function immediately after an implantation or if there is a severe rejection episode. A fundamental misunderstanding not understood by HCFA is that there is a spectrum of levels of expertise necessary to provide adequate care.

We have no disagreement that large hospital-based dialysis units might be compared to free-standing facilities, but there must be a higher level of expertise of care available for every patient. Without that, there will be a decrease in surveillance of patients, an increase in morbidity, and possibly an increase in costs, in true costs, because of more frequent hospitalizations and more extensive complications.

Senator DURENBERGER. Thank you.

Dr. FREEMAN. May I summarize, sir?

Senator DURENBERGER. If you can do it quickly.

Dr. FREEMAN. All right. I would like to emphasize one point. We believe that it would be disastrous to make two major changes very quickly in this program because of the absolute chaos that it would cause on our end. One has to change the understanding of the intermediary, the hospital administration, physicians, and the patients. It would be a very difficult thing to do. If the Congress is under a mandate to make a $100 billion across-the-board cut—and now I am speaking not for our board, but personally—I would favor a simple across-the-board cut and a reduction until adequate information and adequate study could be made. We fear for the implications of these proposed rules would decrease access to care and a decrease of quality of care that would affect not only the patients but institutions, facilities, and personnel that render care. Thank you.

Senator DURENBERGER. Thank you. Who is next, Dr. Blagg? Welcome.

STATEMENT OF DR. CHRISTOPHER R. BLAGG, DIRECTOR, NORTHWEST KIDNEY CENTER, SEATTLE, WASH.

Dr. BLAGG. Mr. Chairman, I am Dr. Christopher Blagg. I am director of the Northwest Kidney Center in Seattle, and professor of medicine at the University of Washington. Like Dr. Freeman, I have been a nephrologist for 24 years, and I drive a 1965 Mustang. [Laughter.]

Senator DURENBERGER. You are lucky. [Laughter.]

I wish I drove a 1965 Mustang.

Dr. BLAGG. And I am testifying also on behalf of Dr. Scribner of the University of Washington. We believe that home dialysis, as you have seen from the figures from the State of Washington, is an effective form of treatment for many patients, and we believe that any changes in the reimbursement in this program must look at the effect on home dialysis and transplantation. I would like, rather than reading my testimony, to just comment on a few points specifically that relate to this.

Senator DURENBERGER. Your testimony will be made a part of the record.

[The prepared statement follows:]

WRITTEN STATEMENT OF CHRISTOPHER R. BLAGG, M.D., DIRECTOR, NORTHWEST KIDNEY CENTER, SEATTLE, WASH.

Mr. Chairman, I am Dr. Christopher R. Blagg, Director of the Northwest Kidney Center in Seattle, professor of medicine at the University of Washington, Seattle, past president of the Renal Physicians Association, and past chairman of End-Stage Renal Disease Network Coordinating Council #2. I am testifying on behalf of the Northwest Kidney Center and also on behalf of Dr. Belding H. Scribner, professor of medicine at the University of Washington, Seattle. Dr. Scribner and his staff at the University of Washington developed much of the equipment and many of the techniques which have made possible the widespread use of both hemodialysis and peritoneal dialysis and were responsible for much of the pioneering work on home dialysis in the United States. As a result, the state of Washington has had a coordinated program for treatment of end-stage renal disease by dialysis and transplantation for many years, a program which has maintained one of the highest rates of home dialysis in the country.

We would like to thank the Subcommittee for this opportunity to submit our comments on the proposed prospective reimbursement rates for the End-Stage Renal Disease (ESRD) Program, particularly in light of our experience in the state of Washington. We believe that home dialysis and transplantation are the preferable forms of therapy for many patients, that these are cost-effective forms of treatment, and that any changes in reimbursement for the ESRD program must take into account the effect on home dialysis and transplantation.

THE ADEQUACY OF THE DATA ON WHICH THE ADMINISTRATION BASED THE NEW RATES

We would like to express our serious concern regarding the data used in setting the proposed rates. The audit data used for establishing the cost of in-facility dialysis dates back to between 1977 and 1979, is used without adjustment for inflation, there is no information as to whether sampling obtained truly representative facilities, and information from these audits has not been readily available for outside analysis. Arbitrary disallowances of 15% for independent and 3% for hospital facilities were made, have not been subject to challenge, and have a significant effect on the final rate.

The data on the cost of home dialysis is more recent (1980) but included 10 of the 13 largest home dialysis providers likely representing the most cost-effective programs. Thus these costs may not be appropriate for small facilities or those starting a home dialysis program.

No information is provided in any of the cost data on the percentage of patients reusing dialyzers, although this is widely practiced and may significantly reduce costs.

It is remarkable that HCFA, despite reliance on this financial data for rate setting, states in the proposed rule that they do not have "a definitive standard for an efficiently and economically operated facility."

The proposed rules also comment on the lack of data on the cost of peritoneal dialysis. Intermittent peritoneal dialysis is used by only a small percentage of patients but is necessary also for support of patients on continuous ambulatory peritoneal dialysis (CAPD). We and others have given cost information on intermittent peritoneal dialysis to HCFA on several occasions in the past, obviously without effect. Also, one might assume that in the audit of 110 facilities, HCFA might have obtained some cost data on peritoneal dialysis or that such information would be available from programs which have asked for cost exceptions for intermittent peritoneal dialysis. Clearly, because of the longer duration of a typical intermittent peritoneal dialysis session (10 to 14 hours), the cost is greater than for hemodialysis, and it would seem essential to establish a separate rate for intermittent peritoneal dialysis.

With regard to the rate for self-care dialysis training, the proposed rule is in error in stating that this has always been reimbursed at a screen set $20 more than the screen for outpatient maintenance dialysis, as in 1973 the rate for a training dialysis was set at $190 per dialysis. HCFA has not audited dialysis training costs, but many of the major training programs, including our own, have exceptions for training, and their rates are significantly higher than that proposed. If congressional intent is to increase the use of home dialysis, it is essential that training programs be adequately reimbursed for their services. The proposed rate is unrealistic, in no way meets the needs of many existing training programs, and will be of little help to facilities starting new programs. HCFA must obtain information on training costs as a matter of urgency, and the rate for training dialysis should then be set at a realistic level.

THE ADEQUACY OF THE RATE SETTING METHODOLOGY

The rate setting methodology used is arbitrary and inappropriate, and as a result, the proposed rules do not meet the statutory provisions and the intent of Congress to develop a dual composite rate. Rather, the methodology used appears designed to insure that the difference between the rates for hospitals and independent facilities is minimal. In the calculations, the median costs for all facilities was used rather than the costs for hospital and independent programs separately, their home dialysis rate of 23.5% was used in calculating the hospital rate while using the independent facility home dialysis rate of 10.5% for independent facilities, again disproportionately reducing the hospital rate (even though hospital facilities clearly are supporting more home dialysis patients, and HCFA's objective should be to increase the use of home dialysis by independent facilities), and application of overhead costs was also used to reduce the hospital rate. As a result, the rates are so close together as to be, in effect, a single rate, despite the clear statutory provision for a dual rate.

The use of the area wage index results in a wide range of reimbursement rates, with a great deal of overlap between hospital and free-standing facilities. In some major cities, the rate will be significantly greater than the present screen rate and therefore is unlikely to be a significant incentive to increase use of home dialysis by independent facilities in those areas.

THE ABILITY OF PROVIDERS TO ADAPT TO THE NEW RATES

If the regulations proposed are implemented, this will cause significant difficulties for providers, patients, and physicians. We are in favor of the concept of a dual composite rate, appropriately developed, but do not believe it is feasible to make the abrupt and significant change in rates proposed and expect providers to adjust instantaneously. The methodology used has resulted in rates lower than those currently charged by significant numbers of both hospital and free-standing facilities; and while undoubtedly many can adjust their operations with time, patient anxieties are increased with regard to their treatment. Certainly, the composite rate does provide a financial incentive to increase the use of home dialysis, but this, too, cannot be expected to develop at short notice. Both in the interests of reducing the immediate impact on the existing ESRD Program and in order to give opportunity for development of good home dialysis programs, it would be better to phase down the reimbursement to the composite rate levels over a period of one to two years.

We see serious problems for facilities in adjusting to the new composite rates by developing home dialysis training programs de novo. The proposed rules note that 10 facilities treat 30% of all home dialysis patients in the United States, and HCFA has data showing that the home dialysis rate for proprietary dialysis facilities is less than 10%. There are several hundred dialysis facilities at this time which do not have home dialysis training and support programs. While it is easy to provide good, efficient dialysis to an outpatient, without the need to provide significant other supporting services, safe and successful home dialysis requires significant support in terms of nurse and technician consultation, social work, equipment service and repair, provisions of supplies, etc. We do not believe that adequate home dialysis training and support services can be developed on a crash basis by a large number of facilities and that if this is forced upon them the result will be poor quality training and inadequate support to patients, leading to failure and return of patients to facility dialysis at increased expense. Consideration must be given to means of encouraging regionalization of home dialysis training and support services, and regulations must address a mechanism whereby facilities can be given credit in their reimbursement for patients referred to other facilities for home dialysis training and support.

THE POTENTIAL EFFECT THE NEW RATES WILL HAVE ON PATIENTS, PHYSICIANS, AND FACILITIES

Patients naturally are concerned because of information that a large number of both hospital and independent facilities face a significant reduction in reimbursement, raising the possibility of closure of facilities, economies in treatment, and possible impact on the quality of the care provided by facilities. However, some facilities appear to be frightening patients by saying that the intent of the regulations is to force patients to go home and by suggesting that home dialysis is not safe. HCFA should know that past experience has clearly shown that patients who have been on facility outpatient dialysis for some time and have become dependent are difficult to change to home dialysis. Consequently, another strong argument for a phase-in period for the proposed rates is that any increased use of home dialysis primarily will come from new patients. The states of Washington, Indiana, and North Carolina, among others, have shown that home dialysis can be achieved by a considerably greater proportion of patients than is now the case nationally. We believe that if rehabilitation data were available (and again, regrettably, good data is not available at this time), this would show that home dialysis patients generally are better rehabilitated and that this is only in part due to patient selection.

The issue of patient safety with home dialysis was raised in a handout used by patients at their meeting at Secretary Schweiker's office some weeks ago. This flyer includes the fact that we have reported a three-year patient survival of 58% at the Northwest Kidney Center--described in the flyer as "much lower than the national average." This same scare tactic of raising concern about the safety of home dialysis because of this figure was used by the representatives of a proprietary dialysis coroporation to delay passage of PL 95-292. As we pointed out when giving this data to Mr. Rostenkowski in 1977, the three-year patient survival of 58% was for all patients in our program and not just for home patients. The "national average" used for comparison was 1974 data from the National Dialysis Registry which clearly represented a different patient population. The present three-year survival for all our dialysis patients is 61%. Data from the ESRD Medical Information System shows a three-year crude survival rate of 52% for dialysis patients, and this is better than the true three-year survival rate because patients dying in the 60- to 90-day preentitlement period are not included. Data from the European Dialysis and Transplant Association also shows a three-year survival for dialysis patients of 61%. Comparison of data for the last 6 months of 1981 from ESRD Networks with high home dialysis rates shows that the death rate is similar for home dialysis and outpatient dialysis patients. We know of no published data showing that home dialysis carries an increased risk to patients.

In the section on Discussion of Alternatives in the proposed rules, it is noted that the composite rate will cost some home dialysis patients more from their own pockets, although for many this will be covered by coinsurance. Several of our patients have expressed concern about the current target rate reimbursement because they know that home dialysis costs appreciably less than the reimbursement. They feel that this difference should be applied to helping the home dialysis patient by providing financial support for the family member or for other costs associated with home dialysis, rather than using this to support patients dialyzing at the facility, some of whom would be capable of home dialysis. These patient concerns will certainly continue.

As published, the proposed rule would eliminate the 100% purchase option for home dialysis machines, which we believe to be an incentive to facilities supporting home dialysis. We question the statutory authority of HCFA to abolish this provision by the proposed rules and urge that this be reinstituted. We are also concerned that the proposed regulations would continue to permit patients to bill for their own supplies. Clearly, this is inefficient and potentially costly; and if the composite rate is to be effective, this provision should be eliminated, if necessary by legislation. We are also concerned that while the composite rate will permit use of funds to support home dialysis aides, if a facility does this, the cost of aides will not be included in rate setting.

With regard to the proposed changes in physician reimbursement, we have always maintained that using the alternate method of reimbursement, physician reimbursement should be the same whether a patient dialyzes at home or in a facility. Further, it should be the judgment of physician and patient as to how often the patient is seen by the physician.

FINAL COMMENTS

The proposed changes in reimbursement, while appropriate in principle, are being implemented too rapidly, with questionable methodology, and without an adequate data base to appropriately set the reimbursement level for hospital-based facilities, intermittent peritoneal dialysis, and home dialysis training.

We recommend strongly that HCFA obtain adequate cost data for all modalities of treatment on a regular basis.

We are particularly concerned that without a separate ESRD office in HCFA, there is no focus to handle the many problems of patients, physicians, and providers and that the ESRD Program will continue to drift without strong direction.

We urge that consideration be given to ways of encouraging regionalization of home dialysis training and support programs in order to maintain quality of care and that means be found to provide credit to facilities that elect to refer patients for training and support elsewhere.

We realize the need to constrain the cost of the ESRD Program but also believe it necessary to make significant changes in these regulations prior to their final issuance. Meanwhile, we suggest implementation of the existing legislative provision that first-year reimbursement become the primary responsibility of major medical insurance where available rather than Medicare; that current exceptions be scrutinized closely, and if not clearly justified, eliminated or reduced; and that if there is to be significant delay in the implementation of composite rate reimbursement, consideration be given to a small across-the-board cut in reimbursement to all facilities.

Successful operation of the ESRD Program requires the availability of prompt and reliable information, both with regard to patient care and the cost of treatment; requires an informed responsive ESRD office in HCFA which can insure sound policy making; and requires further consideration of the non-financial issues involved in meeting the intent of encouraging more home dialysis and transplantation. The present ESRD Program charitably could be described as chaotic, and the danger is that implementation of the proposed regulations as written likely will increase this chaos. The dual composite rate appears to be a reasonable incentive to encourage further use of home dilaysis, but its implementation requires further innovative thought.

Dr. **Blagg**. First of all, with regard to the cost of home dialysis, I firmly believe that the cost of home dialysis is less than that of in-center dialysis if properly done, and there is data to prove this. In the State of Washington for the years 1977 through 1979 part B medicare reimbursement per ESRD patient was approximately 80 percent of part B reimbursement per ESRD patient in the Nation as a whole. I think that represents the savings from the widespread use of home dialysis.

I would like to comment briefly about the regulations where HCFA says it has no data about the cost of peritoneal dialysis. A number of programs have offered to give them this data over the years, and I think they should have some information on which to base list estimates because CAPD, which is used widely, does require IPD as backup. There is also no discussion of the proposed payment for self-care dialysis training, and the cost for this is appreciable. In our own program, where we have a pretty efficient training program that gets patients through in 3 to 4 weeks, it costs something like $2,000 over and above the cost of the dialyses for training. Medicare's suggestion of reimbursement of $20 per dialysis above the screen level for home dialysis training is not practical for existing programs, and certainly not practical for new programs starting home dialysis training.

I won't comment on the data and methodology used by HCFA to calculate rates because others have done this. I will say that we are genuinely in agreement with the concept of a composite rate, a dual composite rate, as a way of providing an incentive for home dialysis, although we do not believe that the present rates are the right ones. But we are concerned about the effect of an instantaneous change that might occur, as we heard this morning, perhaps on July 1. We are concerned about that for two reasons. We are concerned about the hospital programs and what may happen to them, because as you may have gathered from Dr. Davis' data, hospitals provide much of the home dialysis training and support in this country. To put them out of business is not going to do much to help home dialysis. Second, we are concerned that you cannot expect to suddenly develop new home dialysis training programs overnight. The regulations, as they are presently written, would encourage everyone of the thousands of facilities out there to develop their own home training program because that is what they have to do to get enough reimbursement to run their whole operation. We don't believe that is going to work. We are not saying that facilities that want to do this should not be allowed to do so, but to expect them to be able to develop quality training programs and support programs overnight is foolish. It would be much better to consider a phase-in period of time during which these can be developed, the regulations can be looked at as to how perhaps some regionalization of home dialysis training programs can be developed, and a way can be devised by which facilities that do not wish to have their own home dialysis training program can get some credit for the fact that they refer patients to other facilities with such programs.

I would like to make brief comments about patient concerns. One of the issues that has come up is whether patients are going to be driven home by these regulations. Certainly our experience in Seattle over the years has been that patients who dialyze in a facility for a long time are unlikely to go home except in the most difficult circumstances. It is much more likely that if these regulations have any impact it will be on new patients coming into the program and they are the ones more likely to go home.

Regarding patient safety, I would say that there is no evidence that home dialysis is any less safe than in-center dialysis. This issue has been raised in the past, and I believe it was raised again by some patients 2 or 3 weeks ago. In our own program at this time, the 3-year patient survival is 61 percent, which is comparable with the figures from the European Dialysis and Transplant Association. According to the ESRD Medical Information System of HCFA when I inquired 2 weeks ago, the cumulative survival at 3 years for dialysis patients in this country is 52 percent, so I don't believe that a large home dialysis program increases risk to the patients.

Home dialysis patients will have to pay more costs out of their own pocket with the proposed regulations. Patients have already raised this question with us because we use the target rate reimbursement. Our patients ask: Why, when we know it only costs $5,000 or $6,000 a year to do home dialysis if we reuse our dialyzers, are you now getting paid a much larger sum of money to the facility? And we have to respond that it is because this is the way that medicare does it.

We think it is a mistake to eliminate the 100-percent reimbursement for home dialysis machines. We are also concerned that the proposed regulations leave in the patient's option to bill for their own home dialysis supplies because cost effectiveness would suggest that these must be part of the composite rate.

Finally, to close, we would suggest several things. One, there is some question as to how rapidly HCFA should introduce this; second, there must be good cost data on all modalities of treatment; third, as we said at the last hearings, we think there ought to be a specific ESRD office in HCFA to handle this program; fourth, HCFA should look at ways of regionalizing and improving home dialysis training. Meanwhile, if there is to be some delay in implementation of these regulations, first of all, the Senate's provision for first dollar coverage from private insurance ought to be implemented, which has not yet been done; second, HCFA should go out and audit the facilities that have exceptions; and third, HCFA should collect the possibility of an across-the-board cut of a small amount of money per dialysis for all facilities. I would be happy to answer any questions.

[Questions submitted by the chairman and answers thereto follow:]

QUESTIONS SUBMITTED BY THE CHAIRMAN AND ANSWERS THERETO

Question. Hospital-based facilities are more expensive in terms of labor, supplies, and overhead. In your opinion, is there any justification for these higher costs?

Answer. With regard to the issue of whether hospital-based facilities are justified in having higher costs, I would say that at the present time this is justified because of the way in which overhead is allocated by Medicare for hospital facilities as compared with free-standing facilities. However, except as discussed below, I see no reason why, if in the future the accounting system used is the same for both hospital and free-standing facilities, the cost dialysis should necessarily be greater in hospitals. The only exception should be where a hospital facility can clearly be shown to have a different patient population to the average free-standing facility, and this certainly occurs in some instances. However, as you know, the problem is the lack of a good data base to enable comparisons to be made. Dr. Scribner and I feel strongly that eventually the reimbursement for outpatient dialysis should be the same for both hospital and free-standing facilities treating similar patients, but also we feel it is inappropriate to introduce this change without a transition period and without changing the method of overhead allocation in Medicare cost reporting in hospital dialysis units. There also must be a practical exception process. The danger of an abrupt change, apart from concern as to whether this will result in a significant takeover of hospital-run dialysis facilities by proprietary corporations, is the possible adverse effects on home dialysis. Hospital units historically have sent home a much larger percentage of their patients then do free-standing facilities. If the intent of the ESRD Program is to encourage dialysis as a preferred form of treatment for more patients, one does not put out of business the facilities which have been most effective in home dialysis training.

Question. Given an initial equipment and installation cost of $12,000, and interest rate of 18 percent, and a 3-year payback period, it would cost $33.37 per treatment to place someone on home dialysis. That leaves about $95 to cover all other costs. For a 5-year payback period the per treatment cost is about $24. In light of this information, do you believe non-profit and small independent facilities can finance the home dialysis equipment and installation needed to initiate a new home dialysis patient if the 100 percent reimbursement mechanism is eliminated?

Answer. With regard to the question of elimination of the 100 percent reimbursement mechanism for home dialysis equipment, I feel very strongly that this is a mistake. Elimination of this will result in the continuing leasing or renting of equipment, which is more expensive to HCFA in the long run. It is unlikely with the proposed reductions in reimbursement that facilities other than those managed by the larger chains will be in a financial position to go out and purchase equipment directly, and they are likely to maximize their profit by re-leasing the equipment themselves. Thus I believe strongly that the 100 percent reimbursement mechanism should be maintained, and I question the authority of HCFA to abolish this statutory provision by regulation.

Question. To foster home dialysis, should we pay each home patient a set amount, and allow them to pocket the difference between the cost of the equipment and services they need for dialysis an dthe amount they receive? Do you see any problems with this type of approach?

Answer. With regard to the possibility of paying home dialysis patients a set amount and allowing them to pocket the difference between the cost of dialysis and the amount, I have concern. There is a question of fairness in that there are many variables which determine the cost of the equipment and supplies required for home dialysis by a given patient. If the composite rate is to function, it is essential that some of this difference come to the facility in order to compensate for the reduction in reimbursement for outpatient dialysis. In this regard, I also believe it inappropriate to maintain the provision whereby patients can deal directly with a manufacturer of supplies and that cost-containment would be better met by directing purchase through the facility. Patients will be subject to advertising pressures from companies, and while this would permit "competition," the issue of quality of materials and the ability of patients to distinguish the most appropriate materials would be of concern. Rather, if one intends to encourage home dialysis by a financial incentive to patients, consideration should be given to paying the home dialysis patient an attendance allowance, as is currently the practice of the VA and also in Great Britain. My understanding is that in Britain this allowance is nontaxable and amounts to between $30 and $35 a week. Perhaps also if a home patient reuses their dialyzers they should share in the resulting saving.

Question. Recently, ESRD patients have been provided the facts about home dialysis as part of a rally organized to protest the new regulations. Those facts, as they were called, suggest that home dialysis only works for the wealthy, educated, middle class and is not safe. Your statement addressed the safety issue—what about the contention that home dialysis is only for young, white males of the middle class?

Answer. The contention that home dialysis is only for young, white males of the middle class is an example of the scare tactics that have been utilized to oppose the proposed regulations. Many home dialysis programs have patients over the age of 60 (who often make excellent home dialysis patients), patients who are poor, and patients of all races. Each patient's social situation needs to be assessed individually as does their ability to conduct safe home dialysis. In particular, the program at Downstate, New York, has shown that home dialysis can be very satisfactorily performed in the ghetto in Brooklyn. There is a common misconception that in Seattle our home dialysis patients are all Boeing engineers or their spouses when in fact all social classes and races are included in our home dialysis program. A previous study showed that the intelligence quotients (IQ) of our home patients ranged from 79 to 147, with an average of 101. Nationally, there has been a reduction in the proportion of females on home dialysis as compared with males, presumably because of a greater opportunity for females to dialyze by day at a facility whereas working males may have difficulty in obtaining dialysis at a convenient hour. I strongly reject the concept that home dialysis should be limited to a particular subgroup of patients. The decision should be based on the individual patient and their circumstances.

Senator **Durenberger**. Thank you very much. Dr. Deane?

STATEMENT OF DR. NORMAN DEANE, DIRECTOR, MANHATTAN KIDNEY CENTER, NEW YORK, N.Y.

Dr. **Deane**. Mr. Chairman, Senator Baucus, I am Norman Deane. I have been a nephrologist in New York City for 30 years, involved with teaching patient care and investigation. Currently, I am the medical director of the National Nephrology Foundation, which is a public foundation. I have overall responsibility for patient care at the Manhattan Kidney Center and the South Bronx Kidney Center. Without any implication, I should say that these facilities are not chain affiliated. These facilities treat a population of patients which is 70 percent black and Hispanic, with special needs and opportunities. They are, however, unable to engage in home dialysis to the same extent as this can be done in certain areas in the country. I should also say that one-third of our patients do not have medicare eligibility.

What I would like to discuss with you today are some aspects of dialyzer reuse and cost control in the ESRD program. Hemodialysis, as you see in the first illustration, is a process in which blood circulates through a dialyzer, an example of which I have in my hand, and then returns to the body, having been cleansed in the hemodialyzer. One hundred percent of the treatment effect occurs in the hemodialyzer. This is an example of the hollow fiber hemodialyzer [indicating] which is the type most commonly employed in the United States. This is also the type most commonly reprocessed for multiple use in the same patient. Clearly, if one can use the same dialyzer for several treatments there will be economies and there is an implication in terms of total use of consumables in the program. Let's have the next illustration.

Because of this, in Public Law 95-292, Congress mandated a study which would deal with the safety and efficacy of dialyzer reprocessing techniques. The Manhattan Kidney Center was awarded the contract for this study. A final report was provided to NIH in June 1981. Your staff has copies of this final report. The results of the study—let's have the next illustration—show that if one exerts suitable quality and process control while following protocols which we have employed, the multiple used hollow fiber hemodialyzer does not demonstrate properties different from the single use hemodialyzer.

In conclusion, one part of the answer to the question which Congress asked about reuse is provided by the application of this technique. Our survey data show that nephrologists have prescribed multiple use in greater degree during the interval 1978 to 1981, as a result of the enormous cost pressures of the maintained reimbursement screen. There are now 10,000 patients receiving treatment with multiple used dialyzers as judged from a survey which I made in conjunction with other members of the Renal Physicians Association.

Finally, we think that this is an example of new technology that is cost effective, maintains quality, and reduces the frequency of patient's first use reactions.

What implication does this new technique have in overall cost control in the ESRD program? How was it possible to maintain the fixed reimbursement screen? All of us are concerned about the $1.8 billion figure that is cited as the cost of the ESRD program. We have observed the needs of the increasing numbers of ESRD patients that we encounter.

As judged from the accomplishment in 95 percent of independent facilities, of the fixed reimbursement screen, the American nephrologist has performed remarkably in provision of cost-effective, quality-maintaining dialysis service. If you look at the influence of the total medicare component index for the interval 1973–81, it is 2.14. Had the charge for staff-assisted ambulatory hemodialysis floated as the rest of the medical charges, it would now be $284. How has this efficiency been achieved by the nephrologist? By economies of scale, developing new technology and the utilization of cost-effective procedures.

In summary, control of the ESRD program cost confronts us with limited options. We can try to control total program costs by fixing the maximum number of patients treated, as is done in certain European countries. This does not appear to be an acceptable alternative for us. We can control unit costs by new technology, home dialysis, the current fixed screen, and an analysis of the exception process.

I have had an opportunity to review data submitted to HCFA by 187 facilities which have received exceptions to the reimbursement screen. These 187 facilities yielded approximately $40 million per year excess as a result of the exception reimbursement.

I appreciate the opportunity to talk with you, and I will be happy to answer any questions.

Senator **Durenberger**. Thank you very much for your testimony.

[The prepared statement and other material follow:]

STATEMENT BY NORMAN DEANE, M.D., F.A.C.P., DIRECTOR, MANHATTAN KIDNEY CENTER, NATIONAL NEPHROLOGY FOUNDATION

Mr. Chairman, I am Norman Deane, the Medical Director of the Manhattan Kidney Center in New York City.

I plan to discuss with you today some aspects of dialyzer reuse and cost control in the ESRD Program. Multiple use of hemodialyzers is an example of new technology which can assist in cost control in the ESRD Program.

INTRODUCTION

Hemodialysis is a process in which blood leaves the body, circulates through a dialyzer and then returns to the body. While in the dialyzer, the blood is filtered by exposure to dialysate which is discarded. The dialyzer produces 100 per cent of the treatment effect and accounts for 40-50 per cent of the total cost of all disposables used in the hemodialysis procedure.

The hollow fiber dialyzer is the most frequently employed for treatment in the United States. It is also the type which is most frequently employed for reuse.

Why is it desirable to reuse dialyzers? It offers the advantage of cost control with maintenance of quality care. As a result of this potential, further study of the safety and efficacy of dialyzer reuse was mandated by Congress in Public Law 95-292. The Manhattan Kidney Center of the National Nephrology Foundation was awarded the NIH contract to perform this study with myself as the principal investigator.

RESULTS

The results of this study indicated that, insofar as safety and efficacy were concerned, dialyzers reprocessed according to specific standards and protocols provided features equivalent to single use dialyzers.

SURVEY OF APPLICATION

As a result of the demonstrable cost effective and quality maintaining aspects of this new technology, multiple use of dialyzers has increased significantly in the United States.

In surveys which we conducted in 1978 and in 1981, it was determined that the number of patients treated with reused dialyzers had increased more than 200 per cent. Multiple use is practised in 176 facilities with 10,089 patients.

CONCLUSION

The reuse of dialyzers is cost effective, maintains quality and reduces frequency of patient first-use reaction. First-use reaction or new dialyzer syndrome is a pattern of symptoms which some patients experience with the first treatment with new dialyzers. These reactions are eliminated with repeated treatments with the same dialyzer. This is considered to reflect increased biocompatibility of the multiply used dialyzer. This technique is illustrative of a new technology which offers cost effective, quality maintaining features useful in the ESRD Program.

COST CONTROL IN ESRD PROGRAM

The Impact Of Fixed Screen

For 95 per cent of independent facilities, the screen of $133 has been maintained. This represents significant saving in view of the change in the total health care component index which is 2.14 for the interval 1973-1981. Thus hemodialysis charges would have increased $133 x 2.14 = $284.62 were it not for the fixed screen. Maintenance of the screen in view of pressures on health costs reflected the direction of the nephrologists. They achieved (1) economies of scale (2) developed new technology and (3) utilized cost effective procedures.

Control Of ESRD Costs

Options

1. Control of total program costs
   - Fixed maximum number of patients
   - Fixed dollar appropriation

   This option is utilized in certain countries with national health insurance. It does not appear to be an acceptable option for consideration in the United States at this time.

2. Control of Unit Cost of Treatment
   - New Technology
   - Increased Home Dialysis
   - Maintain Current Fixed Screen
   - Severe Limitation of Exception Process

Control of unit costs affords the most acceptable option for control of ESRD costs at the present time. The activities of the nephrologists are determinant in the initial 3 factors whereas administrative control of exception reimbursement is required for implementation of the fourth factor. With a fixed screen, unit cost of ESRD treatment decreases in view of existing health care cost trends. Exception reimbursement, however, is susceptible to these trends. An analysis of exception reimbursement data from 187 facilities indicates an increment of cost equivalent to $40 million per annum due to the exception amount.

QUESTIONS SUBMITTED BY THE CHAIRMAN AND THE ANSWERS THERETO

Question. Hospital-based facilities are more expensive in terms of labor, supplies, and overhead. In your opinion, is there any justification for these higher costs?

Answer. The high cost of hospital based hemodialysis facilities is not justified to the extent which it exists in the ESRD program.

The process for approval of exceptions to the reimbursement screen has not ben analyzed or monitored appropriately. Unless two entirely separate geographic facilities exist, i.e., one facility for in-patient hemodialysis and a separate facility for out-patient hemodialysis, it is impossible to estimate accurately the cost of out-patient hemodialysis since in-patient and out-patient costs are inextricably linked when the same staff, same equipment, same space and same administration provide both types of service in the same area. The hospital-based hemodialysis unit operates within the audit climate of a Part A Provider. From this cost based framework, the incentives are structured which result in the current 10–15 percent increment in health care costs annually.

There are certain hospital-based mehodialysis units (estimated less than 5 percent of the total non-federal ESRD facilities) which function in support of an active transplant program or serving as a back-up facility for a number of satellite units. These special units may present costs which justify an exception. Exception rates should apply to direct costs only and there should be a "cap" on exceptions at a ceiling of 1.5 times the reimbursement screen.

RECOMMENDATIONS

(1) As a target estimate, less than 5 percent of non-federal ESRD approved hemodialysis facilities should receive exceptions to the reimbursement screen.

(2) Exceptions to the reimbursement screen should be limited to 1.5 times the screen reimbursement level.

(3) Hospital-based hemodialysis facilities which have received an exception to the reimbursement screen should be limited to providing no more than 15 percent of their total hemodialysis activity as out-patient ambulatory hemodialysis activity. This would reflect the purported unusual patient mix and specialized function of the facility insofar as back-up and in-patient care is concerned.

(4) Exceptions to the reimbursement screen basically represent a subsidy for ambulatory hemodialysis. This is contrary to the concept of competition in health care.

(5) Hospital-based dialysis units can continue their efforts in self care and home dialysis with control of the exception process for staff assisted hemodialysis. Reimbursement for CAPD, however, should be lower than the overall composite rate. This would reflect the reduced labor cost of CAPD which is much less labor intensive than hemodialysis.

Question. If, without the $138 screen, dialysis charges would have increased by 2.14 times to $284, as you stated, what would have been the basis for such an increase, since the cost of providing dialysis did not rise?

Answer. Maintenance of the $138 reimbursement screen within the framework of a charge-based Part B non-provided system created strong incentives for the development of new techniques which would accomplish cost effective, quality maintaining treatment. This charge-based system creates an incentive for dialysis facilities to contain their costs in order to generate some surplus wich can be utilized for capital improvements or program expansion, which are legitimate health care goals. Unlike a hospital, the independent facility is much to small to sell tax exempt bonds to raise capital for improvements so that its surplus, if any, is crucial to the continued viability of its physical plant. Thus, reimbursement in excess of costs is a necessary element of Part B reimbursement, not an evil which drains the Medicare program of its resources. This is a factor which is crucial in maintaining the efficiency of the system.

If this maintenance reimbursement screen is lowered to a point at which it overwhelms the existing capability to deal with it, hemodialysis facilities will either close or react to the incentives which have been structured by the proposed regulations by converting to the psychology of a cost-based Part A provider. These cost-based incentives are the one which currently produce the 10-15 percent annual escalation in health care costs in the United States. The proposed regulations will have exactly the contrary effect to the desired intent. By skeletonizing services in out-patient hemodialysis facilities, in-patient care of hemodialysis patients will increase. The cost of the program in terms of the annual cost of treatment per patient will accelerate.

The focus which will lead to rational fiscal policies in the ESRD program will be one which concentrates on the unit cost of dialysis treatment. Unit cost of dialysis treatment can be reduced each year by maintaining a fixed reimbursement screen.

For illustration, the case can be stated in an over simplified form. Currently the ESRD program treats 70,000 patients for an annual cost of $1.8 billion equivalent to approximately $25,000 per patient per annum. Were the unit cost of treatment to be halved, the annual cost per treatment would be $12,500 and the total number of patients treated would be 140,000 at an annual cost of $1.8 billion. 140,000 patients represent a reasonable prediction utilizing existing data for the number of patients at which the program will come into equilibrium. The example is not intended to suggest that the annual cost of treatment can be halved abruptly. It is a target and the targe will be reached by annual decrements in unit cost of treatment as accomplished by maintenance of the fixed screen but adjusting reimbursement if appropriate for inflation.

Question. When you conducted your survey to determine the extent of dialyzer re-use, did you find that re-use was practiced in independent facilities more than in hospital-based facilities? And if so, what in your opening is the reason for the difference?

Answer. Reuse of hemodialyzers is practised to a greater extent in independent, out-of-hospital facilities than in hospital-based hemodialysis facilities.

Some of the reasons for this difference might be accounted for in the following:

(1) Hospital based hemodialysis facilities generally treat a mix of in-patients and out-patients. Inpatients may have, as part of their clinical problem, infection or other clinical conditions which might, in the judgement of the nephrologist, mitigate against attempting reuse of hemodialyzers in the facility.

(2) Space for reprocessing of hemodialyzers and suitable quality and process control for the multiple use procedure is more difficult to obtain, as well as more costly, in the hospital based hemodialysis facility as opposed to the out-of-hospital hemodialysis facility. This is another example of the fact that certain measures which are cost effective, quality maintaining treatment measures in out-patient hemodialysis patients cannot be implemented to a satisfactory degree in a hospital based facility.

(3) The out-of-hospital, independent hemodialysis facility, as part of a charge-based system, reacts to the incentives to explore all examples of new technology which are cost effective, without altering the quality of patient care. The incentives for economies do not exist to the similar extent in cost-based Part A hospital-based hemodialysis units.

SUPPLEMENTARY STATEMENT SUBMITTED BY NORMAN DEANE, M.D., DIRECTOR, MANHATTAN KIDNEY CENTER, SOUTH BRONX KIDNEY CENTER, NATIONAL NEPHROLOGY FOUNDATION

SUMMARY

(1) The proposed rules for reimbursement for dialysis services should be withdrawn completely.

(2) The present reimbursement screen and schedule should be maintained.

(3) The exception process should be controlled so that no more than 5% of non federal ESRD units would obtain exceptions. Exceptions for the reimbursement screen.

(4) Charges should not be rendered for routine laboratory studies associated with the dialysis procedure.

(5) Accurate audit date should be accomplished which will meet criteria of acceptability of federal agencies and providers.

(6) Vendors of supplies to ESRD units should be required to submit data relating these charges to cost as providers are required to do.

(7) CAPD reimbursement should be decreased reflecting the fact that this treatment has a lower cost labor component. The reimbursement should be decreased to an extent appropriate for this difference.

(8) New proposed rules including these items for dialysis reimbursement should be presented.

(9) Savings approximating $100 million may be achieved by these measures.

The proposed rules for reimbursement for dialysis services will have effects opposite to the intent of Congress for the following reasons:

(1) The rules are derived from audit data which reflects a lack of understanding of the program and underestimates the actual cost of the dialysis procedures. To this extent, they fail to represent the facts which they purport to represent.

(2) The failure to understand the beneficial incentives which flow from a charge based Part B reimbursement system and the maintenance of cost effective, quality maintaining treatment is a serious problem. It results in fiscal judgment which miss the opportunities for acceptable control of cost of the ESRD program be appreciating the significance of control of the unit cost of treatment.

If the actual costs of a federally mandated social program exceed the project cost, there are at least two explanations:

(1) The number of beneficiaries eligible for treatment under the program is greater than projected.

(2) There is waste or fraud in the program which accounts for the increased expenditure.

The annualized individual patient cost for 70,000 ESRD patients in a program expending $1.8 billion is approximately $25,000 per annum. In the light of changes in the health care component index since the inception of the ESRD program in 1973 this is not an excessive figure and has, in fact, increased far less than health care costs in general. If the number of patients increase, costs of the program will increase proportionately unless the program is structured in such a way as to effect a reduction in the unit cost of treatment by new technology, economy of scale and improved incentives, notably physician incentives.

Stated in its simplest form, were the annual cost of treatment per patient to decrease from $25,000 to $12,500 per annum, the number of patients that could be treated for $1.8 billion would be 140,000 patients. This the figure which current estimates provide for the number of patients at which the ESRD program come into equilibrium. The analogy is not intended to suggest that annual cost of treatment can be halved in the near future. We emphasize that by focusing on reduction in unit cost of treatment we will accommodate the necessary increase in patient population and blunt the annual rise of total program cost.

Consequently, all aspects of the program should be structured to provide incentives for control of annual cost of treatment. This is automatically done by maintenance of a fixed reimbursement screen which allows enough room for efficient operation despite the annual rise in labor, supplies and inflation costs. This fixed screen represents a reduction in the real cost of hemodialysis treatment.

Although there have been a number of suggestions of system wide defects of waste or cheating in the ESRD program, there has, in fact, been no substantial documented evidence that such activities operate significantly on total program costs. As with any program, there are soft areas in which economies can be achieved and there are isolated areas in which abuses have occurred.

Arbitrary slashing of reimbursement without adequate consideration of the limits of the efficient operation of ESRD facilities will result in the independent out-of-hospital facilities being unable to maintain the screen. They will either cease to operate or will react to the policy which HCFA is now creating by developing the techniques of cost based facilities. This will result in the same annual increment of 10–15% in costs which is reflected in the hospitals and a continuing rise in the total cost of the ESRD program (with a rise in unit cost of treatment).

A "cap" in the appropriation for ESRD care and rationing of care, as is now accomplished in the United Kingdom and other countries with national health insurance will be an inevitable consequence.

In addition to structuring incentives in the program to reduce the unit cost of treatment, there are areas where economies can be effected.

A principal one is control of the exception process, since it is estimated more than 300 hospital based ESRD units are reported to be received a reimbursement in excess of the screen. An estimate of the saving which would flow from control of this process is approximately $60–70 million/annum.

Laboratory costs performed as part of the routine dialysis procedure (clotting time, hematocrit, urea nitrogen) and performed in the dialysis unit should not be charged separately. This can account for significant savings.

Restrictive State regulations must be monitored to the extent they impact on incentives for cost effective, high quality ESRD care.

Reimbursement for CAPD should not be equivalent to that of the labor intensive hemodialysis and IPD procedures which have a high cost labor component.

In developing a program in which there is "price control" for purchase of dialysis services by the government, it is totally unrealistic to omit any degree of control on vendors to the providers of the services. At the present time, market forces do not control the price of supplies by the vendors. Vendors, as well as providers, should be required to have charge related costs if the program is to have an internal logic for fiscal reality.

STATEMENT OF DR. WALTER GARDINER, NEPHROLOGIST

Dr. **Gardiner**. Mr. Chairman, I am Dr. Walter Gardiner. I am a nephrologist, trained at Columbia University, the University of Michigan, and Wayne State University. I feel like a kid next to these gentlemen. I have only been practicing as a nephrologist for four years. I am the medical director of two hemodialysis facilities in middle Tennessee, one in Nashville and the other in Columbia, Tenn. I am a nephrologist at the Henry Medical College of Hubbard Hospital. I view the proposed rules regarding the Medicare programs of end stage renal disease a program as illogical, naive, contradictory and, quite frankly, racist. First, the published rules alludes to alleged cost data as a result of an audit. And though the audit was done in March of 1980, which a public rule admits, it fails to point out that the audit was actually for 1978. Could it be that HCFA failed to mention the vintage of their data because that knowledge may have weakened their conclusions?

Second, the rule fails to mention that the ESRD program has a superb record of unit cost containment since its inception when inflation is considered. Third, the rules does not mention that the median payment for hospitals in 1981 was $174, and that for nonhospital facilities was $138. It does not mention that the proposed rate for these facilities will be $132 and $128 respectively. The proposal is to use the mean rather than the average because the proposed lister used the median rather than the average because the median is "a better measure of central tendency than the mean." Why HCFA is so interested in statistical cosmetics is beyond me. What the Congress and the special patients on dialysis need to know is how many facilities are going to close because they cannot get their real costs down to the reimbursement rate, and, moreover, how many patients will lose their dialysis location. Unfortunately, the proposed rules are factually silent on this issue. But, alas, the proposed rules do reassure us that the slack will be taken up by home dialysis. So those new patients and those patients who are already on dialysis can go home and have no problem. It certainly implies that those patients who cannot go home do have a problem. In my opinion, this describes the patients in large cities, especially the elderly, the poor and practically the black and Hispanic patients. In my experience, the vast majority of such patients cannot go home. They cannot go home because of a lack of suitable partners, because of a lack of a suitable domicile, and because it is difficult due to poor basic educational skills. These statements are equally true for home hemodialysis and CAPD patients. The effect of these proposed rules on these patients is even more dramatic than in a general population. Since there are 3,000 as many blacks on center dialysis than there are at home—and those in center dialysis are nearly a decade older than those at home—therefore, the proposed solution to the decrease in facilities for the treatment of ESRD patients—namely, an increase in home dialysis—is, in the main, not applicable to the old, the poor, the black. Even if it was inadvertent, these rules are racist, and if interpreted literally, may mean the death of thousands of elderly, poor and black patients. Thank you.

[The prepared statement follows:]

PREPARED STATEMENT OF DR. W. HERMSWORTH GARDINER, NEPHROLOGIST, MEHARRY MEDICAL COLLEGES HUBBARD HOSPITAL

I am Dr. W. Hermsworth Gardiner, a nephrologist trained at Columbia University, the University of Michigan, and Wayne State University. I am the Medical Director of two hemodialysis facilities in middle Tennessee, one in Nashville and the other in Columbia. I am currently a nephrologist at Meharry Medical Colleges Hubbard Hospital and until recently, was Chief of the Division of Nephrology at Meharry Medical College.

I view the proposed rules regarding the Medicare programs End Stage Renal Disease Program as illogical, naive, contradictory, and frankly racist.

First, the published rule alludes to alleged "cost" data as a result of an audit. Although the audit was done in March 1980, which the published rule admits, it fails to point out that the audit was for 1978. Could it be that HCFA failed to mention the vintage of their data because that knowledge may have weakened their conclusions?

Second, the rule fails to mention that the ESRD program has a superb record of unit cost containment since its inception when one factors in inflation.

Third, the rule does not mention that the main payment for hospitals in 1981 was $174.00 and that for non-hospital facilities was $138.00. It does mention that the proposed rates for these facilities will be $132.00 and $128.00, respectively. The proposal is to use the median rather than the average because the median is a "better measure of central tendency than the ". . . . Why HCFA is so interested in statistical cosmetics is beyond me. What the Congress and the public, especially patients already on dialysis, need to know is how many facilities are going to close down because they cannot get their costs down to their reimbursement rate, and, moreover, how many patients will lose their dialysis location? Unfortunately, the proposed rules are factually silent on this issue.

But, alas, the proposed rules do reassure us. The slack will be taken up by home dialysis. So those new patients or those patients who are already on dialysis who can go home, have no problems. Certainly implied is that those persons who cannot go home, do have a problem. In my opinion this describes patients in large cities, especially the elderly, the poor and particularly blacks and Hispanics. In my experience the vast majority of such patients cannot go home because of: One, the lack of suitable partners; two the lack of a suitable domicile; and three, difficulty with trainability due to poor basic educational skills. These statements are equally true for hemodialysis and CAPD in the home.

The effect of these proposed rules on these patients is even more dramatic than it is one the general population since: (1) there are three times as many blacks on center dialyses than there are at home; and (2) those on center dialysis are nearly a decade older than those at home.

Therefore, the proposed solution to the decrease in the facilities for the treatment of ESRD, namely an increase in home dialysis is in the main not applicable to the old, the poor and the black. Ergo, even if it is inadvertent, these proposed rules are racist and will cause the deaths of thousands of elderly poor and black patients.

Senator **DURENBERGER**. Thank you very much. I want to thank all of you gentlemen for your testimony. I am going to make one observation, that is, your position on the agenda is unfortunate, but it is not as unfortunate as those who follow you, because we are rapidly running out of time. You have come, each of you, with varying reaction to the regulations and I think to the policy changes. And I am going to make just one observation that might be helpful to all of us as we go into the future, and that is that this is probably one of the areas, unlike our $4.2 or $4 billion in proposed cuts in medicare/medicaid, but I do not think—at least it is true of most of us—we are not approaching it in terms of how we narrow the Federal deficit. I think when we started these hearings last year we focused on needed public policy changes. We're learning something from this process lessons that are helpful in other areas as we move from cost-based reimbursement to choice, competition, and prospective payments. I am sensitive to what all of you say about not moving too quickly. I don't believe the direction we're headed is racist. And I don't believe it is necessarily chaotic or disastrous. I just think it is a step in the direction of determining how best to meet this very important and unique need while maintaining high quality and encouraging efficiency. I am curious about an issue Dr. Blagg raised concerning the elimination of 100 percent reimbursement on equipment. Who is it that controls and directs the equipment manufacturers in this country, and what do they have to do with the provision of services?

Finally, I would just suggest to you that characterizing what HHS did as anything approaching the end of the world is inappropriate and not necessarily helpful to the process. What is more helpful is your being positive in terms of how better to approach this problem. And I thank each of you for that particular portion of your testimony today. Thank you all very much.

We have to go to our next panel now, which is Dr. Edmund Lowrie, senior vice president, National Medical Care, Inc., Boston, Mass.; Mr. Robert I. Green, chairman of the board, Community Psychiatric Centers, San Francisco, Calif.; Ms. Juliana Weitig, co-owner and administrator; and Jennette LaChat, who is the head nurse of Shady Grove Dialysis Center in Gaithersburg, Md. Are the members of our final panel here, Dwight Geduldig, Marshall Abbey and Dr. Winchester? Are they also in the room? Do we have enough chairs so that you could just come up here and join us and we can run this as one panel to save ourselves a couple of minutes in transferring bodies? While you are coming up, Dr. Lowrie, why don't you proceed with your testimony?

STATEMENT OF DR. EDMUND G. LOWRIE, SENIOR VICE PRESIDENT, NATIONAL MEDICAL CARE, INC., BOSTON, MASS.

Dr. Lowrie. Yes. Thank you, Senator. My name is Dr. Edmund Lowrie. I am senior vice president for National Medical Care. As noted earlier in the hearings, the increases in the ESRD program costs since 1973 has been due almost exclusively to increases in the number of treated patients, and not due to increased cost per patient. Reimbursement for dialysis to hospitals, however, has increased to about $174 per dialysis treatment last year, but has remained constant at about $138 per treatment to nonhospital centers. As such, the private sector has contributed significantly to the success of the cost maintaining or reducing efforts of the program. Nonetheless, the Inspector General's office persists in applying the most stringent interpretation of part A principles which really do not apply to the conduct of competent business within the private sector. Even so, HHS does not even apply its own formula when computing average reimbursement rates. This chart (I) sir, shows their arithmetic error. Correct use of the formula yields an average rate of about $124 for nonhospitals, not $128 as advertised. HCFA erroneously multiplied the wage/price index by the entire base rate, rather than the labor component, when computing its average rates.

Dr. C. L. Hampers of National Medicare Care called this to their attention in December of last year. Note also that the average rate to hospitals is not $132, but rather $128.

Now some claim, as we have heard earlier this morning, that hospitals treat sicker patients, so perhaps the higher price is justified. This simply is not so. The next chart (II) compares, uses HCFA data to compare patients treated by hospital and nonhospital facilities. The average ages are about the same, as are the sex ratios. Nonhospitals treat slightly more black patients, but there is really no difference in the complication rate—that is, treating complicated diseases. Now, HCFA has confirmed these findings, and also found no differences in hospitalization rates. However, we hear that secondary analysis has suggested that hospital treated outpatients may in fact be hospitalized more frequently. Now, some may interpret this to suggest that they are, therefore, sicker or have higher complication rates. We disagree. Actually, the proper question might be, "That given that the populations are so similar, why is it that outpatients treated by hospitals require more hospitalization?"

The next chart (III) indicates some potential causes for increased hospitalization. One potential reason is provider pressure to use unused bed capacity. Another is physician convenience. It may well be that physicians using hospital-based facilities may simply find it more convenient to hospitalize patients with mild or miscellaneous conditions in order to use hospital resources, house staff and whatnot, to provide a portion of the care. Now, we believe that it is probably this particular reason that may be the most significant. However, note that there may also be increases in hospitalization due to inadequate care—that is, under dialysis. We don't wish to label the hospitals with that, Senator. It is merely the fact that it may contribute to increased hospitalization. And if I could have the next chart, please.

This chart (IV) shows survival curves of patients treated for up to 1 year on different experimental protocol. The bottom two groups have subsequently been deemed to provide inadequate care, or inadequate dialysis treatment. Now, it may well be that the higher percentage of CAPD patients treated by hospitals contributes to the higher complication rate in hospital-registered patients. In this regard, I would like to quote from the European Dialysis and Transplant Registry: "Drop-out rates due to death and abandonment of CAPD were 43 percent at 1 year and 68 percent at 2 years." Similar data have been reported from American centers and are similar to those bottom two curves. CAPD is more expensive than limited care dialysis in all probability, and patients require significantly greater hospitalization. It appears that CAPD in this country has resulted, or is the product of intensive marketing efforts by at least one company which involved in some measure the loyalties—or the purchase loyalties—of a large number of academic and prominent physicians.

Finally, home hemodialysis. We support it when it is in the psychosocial and medical best interest of the patient and when they wish it. The next chart (V), however, compares the medical and demographic characteristics of home dialysis patients with center dialysis patients, using HCFA data. Note that home patients are 7 to 10 years younger, and are predominently male. There are far fewer black persons and far fewer individuals with complicated medical diseases such as diabetes and hypertension. So then, Senator, the home dialysis population—in this country anyway—is a highly select one.

And what does all of this mean? HCFA has estimated that the real cost exceed reimbursement in about 40 percent of facilities, and that would be 50 percent if the reduced average rates are, in fact, true. And this would lead, naturally, to a contraction of center base capacity. But the home dialysis population is a selected one, and many patients may simply not have the free labor to donate to home dialysis. Furthermore, the drop-out rates from CAPD are high, at best, and that worst therapy may well be inadequate for a number of patients. So where will these patients from 40 to 50 percent of the facilities go? If you believe, or I will stop if you wish, sir. I am just going to summarize. I would be glad to quit.

Senator DURENBERGER. All right. Would you summarize quickly then?

Dr. LOWRIE. All right. If someone believes that the program costs are too high, but recognizes that the cost per patient is well controlled, then there is only one way to cut costs, and that is by reducing the number of patients in a system sense by limiting service capacity. And as you have heard earlier, this is commonly done in Europe, and especially in England. Now, if the intent is really to do that, then I believe that it should be done with the full knowledge and consent of society and not through a back door or unacknowledged approach of strangling about 40 to 50 percent of the providers, and at a later date blaming the physicians, the medical community, for failure to provide care. Thank you, and I am sorry for going over, sir.

Senator DURENBERGER. I take it your charts are part of your testimony.

Dr. LOWRIE. Yes, sir. We have submitted rather lengthy testimony and the charts will be a part of it, sir.

Senator DURENBERGER. All right. Thank you very much.

[The prepared statement and the charts follow:]

STATEMENT OF EDMUND G. LOWRIE, M.D., SENIOR VICE PRESIDENT, NATIONAL MEDICAL CARE

Gentlemen, my name is Edmund G. Lowrie, M.D. and I am Senior Vice President for National Medical Care, thank you for permitting me to offer my views before the committee this morning. The Department of Health and Human Services published, as a notice of proposed rule making, (47 FR 6556) on February 12, 1982 methodologies and rates for reimbursing for dialysis services. The ESRD program was originally conceived to provide life saving treatment to those in need regardless of financial means, age, sex and race. It was designed to do away with the "those who shall live and who shall die" committees of the late 1960s and early 1970s which were commonly used to allocate treatment resources. The underlying rationale was to resolve the tragic choice between the allocation of resources and the value of human life. Senator Henry Jackson speaking on behalf of the ESRD section (Section 299I) of what later became Public Law 92-603 said:

> "I think it is a great tragedy in a nation as affluent as ours that we have to consciously make decisions all over America as to the people who live and the people who will die. We have a committee in Seattle, when the first series of kidney machines were put in operation, who had to pass judgement on who would live and who would die. I believe we can do better than that... So I would hope that we would make an effort here, at least a beginning, to approve the amendment so that we can do better than we have done heretofore (118 CONG. REC. 33007, 1972)".

We submit that the proposed regulations are a clear and blatent retraction of the entitlement granted to kidney patients by Section 299I of Public Law 92-603 and restated in Public Law 95-292. The ESRD program has been highly successful in many ways. Although the cost of the program has increased, this has been due almost exclusively to increases in patient numbers - which after all was the original intent of Congress - and not due to increased cost per patient. Cost per patient increased between 1974 and 1980 from $15,000 to $19,000 less than 5% per year - which is less than ½ the inflation rate of the day costs in community hospitals and other measures of health care inflation. This efficiency is in no small measure due to the cost containing efforts of the private secter. According to HCFA cost reports, cost per treatment in hospitals has increased to approximately $174 per treatment while it has remained constant at $138 per treatment in non hospitals. (This approximate cost is even acknowledged indirectly in the NPRM (47-CFR 6578). The allowable home target rate is said to be $116 per treatment. Since this would be 75% of the average facility rate, one half of the patients are treated by hospitals, and the non hospital rate is $138, it follows that the average reimbursement to hospitals is $171.) Further, a gradual shift of patients has occurred so that approximately ½ of the patients are now treated in the out of hospital setting (up from 1/3). Approximately 75% of these non hospitals are operated for profit returning a portion of their revenues to the government in the form of taxes thereby reducing even further the net cost of care. The ESRD program in fact has been a model by which life saving services have been provided to all Americans at a much reduced rate of inflation.

The proposed regulations, however, would undo much of that. They effectively emulate the English health care system which all nephrologists in western countries agree denies care to citizens in need - particularly older patients (defined as 55 years) and patients with other conditions in addition to kidney failure. The regulations seek to achieve marginal cost reduction by capitalizing on the free labor of a patient's family. If the system were to work in theory, however, the free labor pool would increase, driving down the price paid for service in future years. This would cause an ever tightening price squeeze on centers who treat patients with medical complications and those unable to find free labor. Combining this with unrealistically low starting prices which are less than the cost of providing service in 40% of American dialysis units will cause a severe contraction in dialysis capacity. Our current home dialysis population is highly select on medical and psychosocial grounds (see below) and most patients cannot be treated at home. Where then will these disadvantaged individuals receive their dialysis treatments if centers are forced to close?

Success and Costs of the End Stage Renal Disease Program

Some bemoan the costs of the ESRD program, believing they are wildly out of control. After all, the estimated 1980 cost of $1.2 billion is up from $283 million in 1974 representing an average annual increase of 27.2%. But total program costs are the product of two factors - the number of persons treated and the cost per person. Increases in total costs could be explained by growth in either or both of these items.

Table I summarizes total and per capita costs, comparing the latter with other indexes of health care inflation. The cost per patient increased from $14,895 to $19,048 (4.3% per year) between 1974 and 1980. When 1980 cost is adjusted by the Consumer Price Index, however, it actually fell from $14,895 to $11,390. The number of beneficiaries, on the other hand, has increased from 19,000 to 63,000 (22.1% per year), so that the largest portion of increased cost results from caring for more patients. Inflation of per capita costs has been far less than observed in other areas of health care.

What has permitted such a remarkable increase in productivity while containing costs better than the general medical community has managed to do? A cost containing incentive was created by placing a cap ($138/treatment) on the price of service. In other words, Medicare departed substantially from the old "cost plus" scheme traditionally used to reimburse hospitals which is not conducive to effective cost containment.

HCFA cost reports show the average cost of out-patient dialysis in hospital units is approximately $174.00 per treatment. The average rate paid to non-hospital units has remained at $138.00 per treatment since 1974 and 76% of these are operated for profit, returning a portion of their revenues to the public purse in the form of taxes. Hospitals generally design their operations to care for critically ill patients and bill for these services under Part A of Medicare. Insomuchas persons who are not hospitalized do not require intensive care, outpatient physician services are billed under the provisions of Part B. Dialysis services provided to outpatients (in either hospitals or non hospitals) are similarly billed under Part B. As such, hospitals have a convenient avenue for recouping excess costs (under Part A) which may be incurred from providing services to the critically ill.

Table II compares the cost of dialysis in an "average" non profit hospital with cost in a for profit, non-hospital unit. The effect of taxes paid by for profit facilities on the net cost of treatment deserves consideration. Assume that there are two patients requiring precisely the same amount of service. One is dialyzed in an average non profit hospital while the other is treated in an average for profit facility. The service needed is the same, so cost should be the same - assume $126 per treatment. The average non-hospital unit receives the current "screen" of $138, leaving $12 "gross profit". About one-half of this sum will be returned to the public as taxes, leaving a net profit of $6, and the effective cost to the public is only $132. The average hospital receives $174 per outpatient treatment and pays no tax. The actual premium paid to the non profit hospital is therefore $42 per treatment. It receives a dual subsidy - a $36 price subsidy and a $6 tax subsidy. The taxpayer ultimately bears the double burden. Note, also, that the effect of any rate increase to for profit units will be reduced by the payment of taxes even if costs were constant. Similarly, any reduction in cost will increase "profit" and therefore taxes. The tax laws, then, provide a convenient mechanism by which increased efficiency (reduced cost) can be shared with the public on nearly 50-50 basis.

In summary, then, cost containment in the ESRD program has been better than in the medical community at large even without considering the taxes paid to government by profit making units. The program has been very successful in providing care to all in need and remarkable efficiencies have been achieved - due in no small measure to the contribution of non hospital units operated for profit. Any reimbursement system which insulates the inefficiency of high cost providers - be they hospital or non hospital - can only force ESRD program expenditures higher.

Cost Finding and Rate Setting in the ESRD Program

The Inspector General of HSS and some elements within HCFA persist in implying the most stringent of Medicare Part A principles to cost finding and rate setting. These cannot be reasonably applied to the real life world of the private sector and many health economists believe that these Part A principles constitute one of the major reasons for health care cost inflation. Their application to the private secter is inappropriate.

With respect to independent facilities, HHS admits that 15% of reported costs were eliminated, thus reducing the total base cost from $126.66 to $107.66. The raw data do not clearly indicate what categories of expenses were excluded, but we do know that three major items were eliminated. First, the cost data excludes normal bad debt write-offs. Under Part A reimbursement principles such eliminations make sense, because the bad debts are restored dollar-for-dollar by Medicare retrospectively. In this sense, bad debt is thus a separately reimbursed item. However, under the present and proposed ESRD reimbursement system, uncollectible receivables, i.e. "bad debts", are indeed real costs of doing business. There is no way that the Securities and Exchange Commission would permit a company such as NMC to report earnings which did not reflect this cost item. If all other costs of a provider were exactly covered by the proposed $128 rate but the provider could anticipate based on its past experience that it would experience a bad debt expense of $3 per treatment, the provider would not be able to participate in the program.

There is absolutely no statutory or logical basis for excluding bad debts.

Similarly, there is no legal authority for excluding a fair return on equity from the cost basis. Even Part A reimbursement principles allow such a return on equity. If all other expenses were covered by the $128 rate, a facility would still not participate in the program if it could not recover some return on its capital investment commensurate with the opportunity cost of investing that capital in other endeavors. Moreover, the exclusion of such a return from the cost basis is illogical when one considers that interest on debt financing would be included as an appropriate expense. Thus, a $1 million facility could legitimately increase its costs by, say, $150,000 per year by borrowing the capital from a commercial lender. This exclusion, then, does not fulfill the Congressional mandate to devise an economical system, and in fact violates both the Social Security Act and existing HHS regulations.

Thirdly, the HHS cost data for independents exclude so-called "excessive" compensation for managers, many of whom are also proprietors or partners in owning the facility. There is no justification for these exclusions. It could well be that an otherwise efficient low-cost provider does pay larger than normal salaries to its chief executive. Why should HHS care about the range of expenses in any particular category, when the "bottom-line" is within the screen? HHS is here mixing a statistical method of setting a screen by fixing the rate at the median of all costs with a modular method of comparing individual expense items with the "normal" amounts for such items. This is not only unreasonable, but such an approach infuses an inflexibility into the system which disincents providers from trying new approaches to reduce total costs. It may well be that only by paying an "excessive" salary can a facility attract top-quality managers who are able by virtue of greater managerial skill and effort to reduce overall costs. We believe this homogenization of cost data by HHS to be unnecessary and potentially counterproductive as well as inconsistent with Congressional intent. Another similar example is the exclusion by HHS of costs of providing office space at the facility for physicians who function as administrators and managers. The exclusion of these expenses is wholly unreasonable.

In general the audited costs are suspect because no facility was given the opportunity to challenge the cost exclusions of HHS. Moreover, the cost audits were performed by various agents throughout the country, and from even a cursory view it is obvious that the audits were inconsistent. For HHS to base prospective rates based on such faulty data which was not even reviewed by the industry prior to the publication of the NPRM and which even today is difficult to obtain (it took us over 6 months to obtain data which the NPRM states were available) and analyze is clearly inconsistent with Congressional intent and violative of administrative procedures required in rulemaking and rate setting.

Aside from the data's inadequacies, they are clearly 5 years old. The NPRM proposes rates for FY 1983 based on cost data for the period 1977-1979, yet except for the de minimis "fudge factor" of 1.05 applied to hospital costs, discussed above, HHS does not adjust the cost data for inflation. Based on health care industry experience such an inflation factor could, conservatively, be set at 50-60%. HHS believes that the non-labor component (roughly 59% of independent's cost and 65% of hospitals' cost) has not been affected by inflation. Although we disagree with this assertion, applying a 50% inflation factor to labor costs alone would raise the target rates by 21% for independents ($155) and 19% for hospitals (158$). Our own experience underscores the need for such inflation factors. We are widely recognized as the most efficient provider of dialysis services and have worked hard to maintain profit margins in a time of unprecedented inflation without any increase in the $138 screen. Nonetheless, between 1978 and 1981, despite the fact that our patients to staff ratio increased from 4.6:1 to 5.7:1 during the 3-year period, our total patient care labor costs increased by 46%, or roughly 15% per year per treatment. In other words, despite our best attempt to fight inflation by improving staffing ratios by 24%, we still experienced a large increase in labor costs. We sincerely believe that our experience is better than other providers in the industry.

Not only are the cost bases for setting the facility rates stale and inadequate, but the cost basis used for home dialysis is clearly skewed. In deriving the $97 cost base, HHS used cost data from less than 5% of ESRD home programs and included 10 of the 13 largest and most efficient programs. Even in this unrepresentative sample the range was very large ($63 to $156 for hemodialysis and $54 to $202 for CAPD). Consequently, the $97 median is meaningless when applied to all hospital-based and independent facilities nationwide. The effect of this is dramatic, especially on hospital providers. Assuming the home cost is understated by 30% (a fairly reasonable assumption considering the above factors) this reduces the composite rate for hospital-based facilities by approximately $7 per treatment. Moreover, as discussed below, the labor component for home dialysis of $12 per treatment excludes the cost of a paid assistant. Clearly, if 35-40% of all dialysis patients are to be dialyzed at home, many if not most will require the services of a paid aide. For those whose assistant is unpaid (e.g., spouse), the system fails to recognize the opportunity cost involved. Apparently, HHS believes that 40% of dialysis patients have a family member capable and willing to attend the patient during 3, 5-hour sessions per week. There is no support for this assumption. HHS believes that the financial incentive to send patients home is so great that facilities will provide a paid assistant at no charge. We see no basis for this belief.

Finally, the average rate calculations performed by HHS contain arythmatic errors shedding doubt on the whole rate setting process. The correct and erroneous calculations for average rates are tabulated below.

CALCULATION OF RATES TO INDEPENDENTS

FORMULA

(WPI x Labor Cost) + Non Labor Cost = Rate

Average WPI = 1.04179

Average Rate + (1.04179 x $49.61) + $72.09 = $124.58

Wrong Calculation:

Wrong Rate = 1.04179 ($49.61 + $72.90) = $127.63

Correct Average Rate for Hospitals = $128.33

≠ $132

Note that HHS seems to have multiplied the entire base rate ($49.61 + $72.90 = $122.51) X the WPI when estimating average rates. So the average rates are $124.58/123.3 not $128/$132. This erroneous procedure was cle Davis to Secretary Schweiker outlining options for these methodologies. Further, the error was called to the attention of the Secretary by Dr. C. Hampers, Chairman of the Board of NMC on December 11, 1981 but was nonetheles regulations.

Hospitals and Non Hospitals

Note that hospitals are paid a higher rate than non hospitals. Proposed regulations published on September 26, 1980 but later withdrawn also propose this dual rate structure. The reaction from the medical community was instantaneous and adverse. The Office of Wage and Price Stability opposed any dual rate structure (Appendix A 1) as did the office of Managment and Budget (Appendix A 2) under the Carter Administration. Health Economist Alan Enhoven says:

> "It is simply not fair competition if government systematically pays more on behalf of similar people who enroll with one type of competitor than with another (Health Plan, page 77)."

We agree but others say that hospitals treat sicker patients, this is simply not so. Table III shows that the average age of hospital and non hospital treated patients is approximately equal and each treats equal numbers of males and females. Non hospital units treat more black patients but the frequency of diabetes and hypertension is equal in both classes of facility. The Health Care Financing Administration has published similar findings (47 CFR 6564). They examined the age, sex and race of patients treated in hospital and non hospital facilities and found no difference. In addition, they evaluated discharged and days of hospital care between hospital and free standing facilities and again found no differences suggesting that there was no difference in required hospitalization between patients treated routinely in these two settings. Nonetheless, we understand that secondary analysis have suggested that patients treated in hospital units may, in fact, be hospitalized more than patients routinely treated in free standing facilities. This possible observation has been interpreted by some to suggest that patients receiving routine treatment in hospitals, in fact, have greater base line medical illness than individuals treated in free standing facilities. The interpretation, however, is both wrong and medically naieve. There are several potential causes for patients experiencing excess hospitalization. These are:

- Inadequate dialysis treatment
- Physician convenience
- Greater baseline medical risk
- Provider pressure

Providers may place pressure upon physicians to use services which would otherwise be unused, thus generating revenues for the institution. Similarly, physicians treating patients in hospital based dialysis units may simply find it more convenient to treat routine or miscellaneous medical conditions as an inpatient rather than an outpatient. In this way, they can use house staff and other hospital resources to provide a portion of the care. Finally, recent evidence has suggested that patients receiving inadequate dialysis treatment will experience greater complication rates and greater rates of hospitalization than patients receiving adequate treatment[1]. Two of the experimental groups in this study have subsequently been considered to represent inadequate treatment and thereby required excess hospitalization. Simply stated, excessive hospitalization by outpatients routinely treated in hospital units can be interpreted in a number of ways. The proper question might well be,

> If the populations are similar with respect to age, sex, race and the presence of diabetes and hypertension, why are patients treated by hospitals hospitalized more frequently?

Chronic Ambulatory Peritoneal Dialysis

The proposed rules extol the virtues of both home hemodialysis and chronic ambulatory peritoneal dialysis. However, recent evidence (Appendix B) submitted from the European Dialysis and Transplant Association indicates that:

> "Dropout rates (death and abandonment of CAPD) were 43% at one year and 68% at 2 years."

These extraordinarily high dropout rates are very similar to the inadequate treatment groups of the reference cited above.

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[1] Lowrie, Laird, Parker, Sargent: The Effect Of The Hemodialysis Prescription on Patient Morbidity: Report from the National Cooperative Dialysis Study. NEJM: 305:1176-1981

Home Dialysis

We support the use of home hemodialysis when it is in the psychosocial and medical best interest of patients. The United States has done well in this regard. Although the average age of European dialysis patients is about 6 to 7 years less than in the United States, the fraction of patients on home dialysis is not terribly different (Combined Report of Dialysis and Transplantation in Europe, X) - 17.5%. Home dialysis percentages in European countries range from 0% to 64%. The median country has 3% on home dialysis and the largest percentage is found in England. The next highest is 20% and if England is excluded the European home dialysis population falls from 17.5% to 13.5%.

Medical and demographic factors influence the choice of dialysis or transplantation and ample evidence suggests that socioeconomic, demographic and medical factors may well influence the choice of home or center dialysis as well. An analysis of HCFA data containing over 44,000 records showing characteristics of patients and their treatment setting is shown in Table IV. The data indicate that, when compared to center patients, home dialysis patients are young, white, and male and their primary diagnosis is less likely to be associated with medical complications. Unlike the comparison between hospital and non-hospital dialysis which shows similar populations, this comparison suggests that home dialysis patients are a highly select group. Their demographic characteristics suggests that they are likely to be more stable, more active in social affairs and have a better rehabilitation and survival potential even prior to starting dialysis treatment.

Regulations Constitute an Effective Entitlement Cut

The proposed regulations constitute an effective entitlement cut. HCFA estimates that real costs will exceed reimbursement for about 40% of all facilities and patients. At the actual rates of $124 and $128, other HCFA data show that costs will exceed the rate in 53% of hospital and 32% of non hospitals (46% of all facilities). This will clearly lead to a contraction of center based capacity. But the home dialysis population is a select one and many patients - particularly the disadvantaged patients - do not have facilities or partners permitting home dialysis. HCFA has not judged a home dialysis nurse to be an allowable cost. At best, the dropout rates from CAPD are high and at worse the therapy is simply inadequate for most patients. So, where will 40% (or 46%) of the patients go?

The effect and probably the intent of these regulations clearly is to cut entitlement. After all, if you believe that program costs are too high but recognize that cost per patient is well contained, the only way to cut costs is to cut the number of patients. In other words, cut entitlement by cutting access to care. Harvard and MIT researchers, Prottas, Segal, and Sapolsky believe that this is a common approach in Europe. Quoting from their summary:

> "Most of the remaining differences in rates (ie, dialysis treatment rates) appears to be due to European policies that prohibit or severely limit access to dialysis by the elderly and those potential patients with significant medical complication."

and from later in their paper:

> "Suggestions have been made that certain nations, Great Britian in particular have made conscious decisions to restrict dialysis to the most likely to benefit from it. Selection criteria seems less a product of direct government fiat than the result of resource constraints making selection necessary."

and

> "The United Kingdom which has one of the lowest dialysis prevelance rates (53 per million) has been rationing treatment for renal failure. It appears that this rationing is induced by general constraints on the resource allocation to dialysis and is not in its specific details centrally directed."

Please note that the United States has about 200 million on dialysis and finally

> "The fact that the British rely quite heavily on home dialysis is also said to result in more restrictive selection policies as requirements for admission to home dialysis are evidently more stringent than those for hospital dialysis".

HHS may have studied this method of limiting access to life saving medical care or perhaps these regulations are just some form of misguided mistake. The persistent arithmatic errors suggest that it might be. But if the true intent is to cut entitlement for current and/or future patients then the decision should be made with the full knowledge of society - not through this back door approach of strangling 40% of of the providers and later blaming the medical community for failure to provide care.

Our specific recommendations to HCFA are contained in a letter commenting upon the regulations. We would be pleased to share a copy with the committee.

TABLE I

Costs and Per Capita Expenditures in the End-Stage Renal Disease (ESRD) Program as Compared with Other Economic Indicators

Year	Average Enrollment	Costs of the ESRD Program			Per Capita Average Annual Payments (in current dollars)					
		In Current Dollars [1] (millions)	Deflated to 1974 Dollars [2]		ESRD Benefits per Capita		Health Care Expenditures [3]		Cost per Patient-Day in Community Hospitals [4]	
	No. of Pts.		Total (millions)	Per Capita	amount	% inc.	amount	% inc.	amount	% inc.
1974	19,000	$283	$283	$14,895	$14,895	-	$534.63	11.8	$113.55	10.9
1975	27,000	450	412	15,259	16,667	11.9	603.57	12.9	133.81	17.8
1976	35,000	598	518	14,800	17,086	2.5	674.14	11.7	152.76	14.2
1977	41,000	757	616	15,024	18,463	8.0	754.81	12.0	173.98	13.9
1978	47,000	947	716	15,234	20,149	9.1	835.57	10.7	194.34	11.7
1979	56,000	1,091	740	13,214	19,482	-3.3	936.92	12.1	217.34	11.9
1980	63,000 [5]	1,200 [5]	718	11,390	19,048	-2.2	1,067.06	13.9	245.12	12.8
Average	-	-	-	-	-	4.3	-	11.9	-	13.7
6-Yr. Change, 1974-1980(%)	44,000	917	435	3,505	-	27.9	-	97.7	-	115.8

[1] Maintained by the DMCE/OFAA/ORDS/HCFA/DHHS.

[2] By setting the Composite Consumer Price Index for 1974 at 100. The CPI was 147.7 and 247.0 for 1974 and 1980, respectively.

[3] National health-care expenditures in 1980 were $247.2 billion which represented 9.4% of the Gross National Product, (up from 8.9%): Gibson, R. and Waldo, D.: National Health Expenditures. Health Care Financing Review, Sept. 1981.

[4] Hospital Statistics. American Hospital Association.

[5] Testimony of Carolyn Davis before Subcommittee on Health of the Senate Finance Committee, 9/28/81.

TABLE II

Income Statement Net Cost for a For-Profit and Not-For-Profit Facility

($ per Treatment)

	For-Profit, Free-Standing		Non-Profit Hospital	
Revenue:		$138		$174
Less Costs:				
Personnel	$40		$40	
Supplies	50		50	
Support Costs	36		36	
		-126		-126
Pre-Tax Income		12		48
Less Taxes @ 50%		-6		-0
Income (Net Profit)		6		48
Gross Cost		138		174
Return		-6		0
Net Cost		$132		$174

TABLE III

Demographic Characteristics of Patients Treated by Hospitals and Non-Hospitals

Characteristic	Hospital	Non-Hospital
Age (mean years)	53.4	53.7
Sex:		
% Female	43.9	45.9
% Male	56.1	54.1
Race:		
% Black	24.4	33.7
% White	72.4	63.9
% Other	3.2	2.4
Diagnosis:		
Often associated with medical complications:		
% Diabetes	10.6	10.8
% Hypertension	17.4	22.1
Usually not associated with medical complications:		
% Glomerulonephritis	28.1	26.4
% Polycystic	9.3	8.7

TABLE IV

Characteristics of Patients Treated by Home and Center Dialysis

	Hemodialysis	
Patient Characteristic	Center	Home
Age (median years):		
When started dialysis	53.1	44.8
Current (mid 1980)	56.1	49.2
Sex:		
% Male	54.4	62.2
% Female	45.6	37.8
Race:		
% Black	30.8	11.9
% White	66.2	85.1
% Other	2.9	2.9
Diagnosis		
Often associated with medical complications:		
Diabetes	11.2%	6.8%
Hypertension	20.8%	9.9%
Usually not associated with medical complications:		
Glomerulonephritis	26.3%	36.9%
Polycystic Kidney Disease	8.6%	13.3%

Table V

HOME DIALYSIS COST PER TREATMENT

FACILITY	NET OF DIRECT PATIENT CARE LABOR	WITH AVERAGE LABOR	WITH SKILLED ASSISTANT	NUMBER PATIENTS
1	$127	$162	$174	25
2	124	149	164	42
3	125	146	175	67
4	111	128	141	19
5	134	184	183	95
6	64	83	96	45
7	128	153	173	106
8	96	108	118	90
MEDIAN	124.50	147.50	168.50	56
MEAN	113.62	139.50	153	60.9
PATIENT WEIGHTED MEAN	116.39	141.94	156.68	- -

APPENDIX A-1

A-1(a)

THE WHITE HOUSE

WASHINGTON

September 30, 1980

MEMORANDUM FOR GEORGE EADS
TOM HOPKINS
GIL OMENN
JIM MONGAN
JIM TOZZI

FROM: DENNIS RAPP DR

SUBJECT: HCFA's proposed "incentive" reimbursement system for Medicare outpatient maintenance renal dialysis and self-care dialysis training treatments

HCFA issued a NPRM on September 26 that would establish a multiple rate basis for prospective reimbursement to providers for outpatient maintenance renal dialysis and self care dialysis training treatment. (There is a different reimbursement basis for inpatient dialysis).

The rule does not set the rates but would establish the basis for setting them.

While redesign of the Medicare payment system to create greater incentive for cost-effectiveness and to hold down the budget cost of the program is certainly desirable, I cannot believe that moving from a single to a multiple rate system as the basis for setting rates for this service is cost effective. It seems to me to be just the opposite. Outpatient maintenance renal dialysis is the only service for which Medicare now has a prospective rate; everything else is paid retroactively. The present rate is $138.00 per treatment. Under the proposed rule, HCFA would set a separate rate for hospital-based dialysis facilities, and one for non-hospital based or independent facilities. There would be further differentiation of these two rates for hospitals and for independent facilities located in rural and in urban areas.

Although the proposed rule recognizes that hospital based outpatient dialysis treatment is consistently more costly than independent facilities, HCFA is proposing to set an "incentive" rate for outpatient dialysis which perpetuates this cost ineffectiveness. Conceptually, this seems to be totally contrary to the objective of prospective rate-setting. Prospective incentive rates should instead be set using the most cost-effective delivery system as the basis for determining the rate, and then only a single rate should be used.

A1 (b)

In addition, the proposed multiple rate will produce much higher Federal budget costs. I am told that based on the present mix of patient-use of hospitals and independents for outpatient dialysis, and assuming that the average prospective rate to be set for hospitals will be about $170.00 per treatment, (a conservative experience estimate at the 75th percentile) and that the rate for independents will remain at the present $138.00, the incremental budgetary effect alone will be about $150 million annually.

Doesn't the rule require a regulatory analysis under the terms of E.O. 12044?

It seems to me this proposed rule deserves careful regulatory review, possibly qualifies for RARG intervention, and certainly justifies CWPS intervention.

It's conceivable that we may want to set up a special review process for redesign of the Medicare payment system to make certain that the approach to prospective reimbursement, with or without incentive features, is not conceptually misguided.

Attachment

APPENDIX A-2

12 NOV 1980

Honorable Blair Townsend
Deputy Assistant Secretary, Budget
Department of Health and Human Services
Washington, D.C. 20201

Dear Ms. Townsend:

We have reviewed with interest the proposed new method of reimbursing dialysis facilities under Medicare which was published in the Federal Register of September 26, 1980. Although we welcome the initiation of prospective reimbursement for these facilities, the methodology for establishing the rate raises some questions. Specifically, the establishment of different rates for free-standing facilities and hospital-based facilities, without evidence clearly establishing that such rates are justified by different case mixes, may tend to undermine one of the purposes of prospective reimbursement--assurance that care is rendered in the most cost-effective manner possible. Fred Kahn's office has expressed similar concerns.

Accordingly, I would appreciate the Department considering issuing a prospective rate that does not distinguish between hospital-based and non-hospital based facilities and that is based on the costs actually experienced in efficient non-hospital facilities. Exceptions could be granted in cases where facilities could demonstrate that a higher rate was justified on the basis of case mix and other variables. In addition, because of the potential budget impact of these regulations, I request that the Department submit the revised proposed rule to us prior to issuance, for review along with an estimate of the budget impact.

Sincerely,

GILBERT S. OMENN

Gilbert S. Omenn
Associate Director for Human Resources, Veterans and Labor

Official File - Health Branch-HIMD
Director's Chron
Mr. Cutter ~~Mr.~~ Omenn
Mr. Berman Mr. Tozzi
Mr. Etheredge Mr. Nexon

HD:DNexon:plh 10/28/80

CHART I

CALCULATION OF RATE TO INDEPENDENTS

FORMULA

(WPI x LABOR COST) + NON LABOR COST = RATE

AVERAGE WPI = 1.04179

AVERAGE RATE = (1.04179 x $49.61) + $72.09

= $124.58

WRONG CALCULATION:

WRONG RATE = 1.04179 ($49.61 + $72.90) = $127.63

CORRECT AVERAGE FOR HOSPITALS = $128.33

≠ $132.00

CHART II

DEMOGRAPHIC CHARACTERISTICS OF PATIENTS TREATED BY HOSPITALS AND NON-HOSPITALS

CHARACTERISTIC	HOSPITAL	NON-HOSPITAL
AGE (MEAN YEARS)	53.4	53.7
SEX:		
% FEMALE	43.9	45.9
% MALE	56.1	54.1
RACE:		
% BLACK	24.4	33.7
% WHITE	72.4	63.9
% OTHER	3.2	2.4
DIAGNOSIS:		
OFTEN ASSOCIATED WITH MEDICAL COMPLICATIONS		
% DIABETES	10.6	10.8
% HYPERTENSION	17.4	22.1
USUALLY NOT ASSOCIATED WITH MEDICAL COMPLICATIONS:		
% GLOMERULONEPHRITIS	28.1	26.4
% POLYCYSTIC	9.3	8.7

CHART III

CAUSES FOR INCREASED HOSPITALIZATION

- INADEQUATE TREATMENT
- PHYSICIAN CONVENIENCE
- SICKER PATIENTS
- PROVIDER PRESSURE

CHART IV

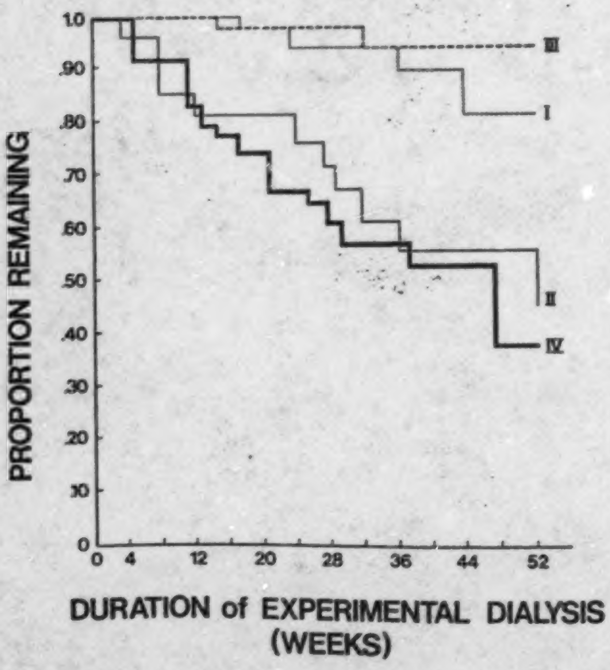

CHART V

CHARACTERISTICS OF PATIENTS TREATED BY HOME AND CENTER DIALYSIS

PATIENT CHARACTERISTICS	CENTER	HOME
AGE (MEDIAN YEARS)		
WHEN STARTED DIALYSIS	53.1	44.8
CURRENT (MID 1960)	56.1	49.2
SEX:		
%MALE	54.4	62.2
%FEMALE	45.6	37.8
RACE:		
%BLACK	30.8	11.9
%WHITE	66.2	85.1
%OTHER	2.5	2.9
DIAGNOSIS		
OFTEN ASSOCIATED WITH MEDICAL COMPLICATIONS:		
DIABETES	11.2%	6.8%
HYPERTENSION	20.8%	9.9%
USUALLY NOT ASSOCIATED WITH MEDICAL COMPLICATIONS:		
GLOMERULONEPHRITIS	26.3%	36.9%
POLYCYSTIC KIDNEY DISEASE	8.6%	13.3%

Question. Profit sharing is a fairly strong incentive, particularly when the dollars involved, as they are for some facilities, are in the $300,000 range. In the interest of profits and for the stockholder's benefit, medical decisions may be made which are not in the best interest of the patient. What mechanisms are employed in your facilities to prevent this from happening?

Answer. Your questions addresses the issue of profit sharing by physicians. Doctor Hampers and I have recently published our views about this subject in the New England Journal of Medicine and I enclose a copy of our article for your information. Portions most relevant to your questions are underlined. Briefly, non-profit hospitals do make profits. Physicians realized no direct gain from these, so are motivated to expend hospital resources without penalty in order to enhance their practice. There is no effective cost-benefit analysis or motivation in this decision making process. Reference No. 23 in the paper addresses this issue quite well and it is discussed near the end of the article. The clear implication is that one must give the physician a stake in those decisions which effect the cost of service, motivating him or her to lower cost consistent with good medical practice. Who else is better qualified to make those delicate, technical cost-benefit decisions? One might argue that physicians should all be salaried but the effect of this would be to eliminate productivity. The economic principle of utility suggest that the incentive here would be to reduce work and maximize leisure because income is fixed. The Veterans' Administration Hospitals, while serving a useful social goal, are not generally regarded as being terribly cost effective. The policy issue then is one of structuring motives for the decision makers so that they can made medical decisions in the best interest of patients. Policy should not attempt to enforce arbitrary, external controls. Although society in general and patients in particular often are ignorant of the subtle forces motivating medical (both hospital and physician) behavior, they clearly understand the meaning of profit. If society and patients can accept a physician's integrity under a fee for service system, there should be little problem with the acknowledge sharing of profits.

Physicians working with a profit share are clearly motivated not only to maintain their practice through providing excellent medical care but also to control the costs of the facilities which they run. The incentive is to learn about cost control and to focus medical expertise on decisions involving cost-benefit tradeoffs. We refer again to Reference No. 23 and note that physicians who run our dialysis facilities are responsible for patient care and cost control. A "two-company environment" which is probably the root cause of escalating hospital costs does not exist in our facilities, which enables us to control costs while providing high quality care.

Few, if any, individual physicians receive an annual profit share of $300,000. A profit share may be distributed in one year having been earned over several years. Even though a profit share may be recorded in the name of a single physician, the may be obligated to distribute portions of this to associates who also assume managerial responsiblity for artificial kidney centers. We hasten to point out that the "five Mercedes" story which so aroused Senator Dole actually occurred in non-profit dialysis units in Florida.

Physicians determine medical policy in our dialysis units. They are not motivated by the needs of our stockholders. They are highly responsive, on the other hand, to the needs of patients with whom they are in constant contact. These physicians are highly respected in their communities and are affiliated with credible institutions who also evaluate the performance of both the physicians and our facilities. We simply could not mandate an inferior form of care. Chronic ambulatory peritoneal dialysis, for example, has been evaluated in a number of our units and many of these physicians have discontinued or minimized its use. Data has now emerged from both the United States and Europe which show that hospitalization rates and death and abandoment rates of CAPD are inordinately high. We simply could not and would not mandate CAPD in pursuit of economic gain and still maintain a credible professional relationship with our medical directors.

Finally, National Medical Care supports a Medical Information System which analyzes medical data from each of our dialysis units. This is summarized and distributed to our physicians for their use in evaluating the performance of their own facility. For example, laboratory data are analyzed for each unit and compared to national norms. The data are correlated with elements of medical practice and results of these analyses are shared with medical directors. They use this information to improve the quality of medical care. This experience is shared with all other facilities, thereby improving the quality of practice for the company in general. I stress, however, that the Interpretation of this material and any action which might result therefrom is at the discretion of the physicians who manage the units and is not centrally directed. In addition we maintain a complete medical risk management system to monitor the care with which therapy is delivered.

Our focus has been to structure incentives permitting health care professionals to make appropriate cost benefit decisions consistent with the medical and social interest of patients and to support them by information sharing. We have not relied on direct medical controls. However, if the laboratory profile of a dialysis unit departs significantly from the usual norm on several occasions or if risk management reports show an unusually high number of incidents, we will call this to the attention of the facility and request an explanation. In reality this represents monitoring by exception and feedback quality control. It is significant in this regard that there has never been an allegation of inadequate care by National Medical Care in spite of the fact that we have undergone extreme scrutiny for at least 10 years.

I hope this rather lengthy response has addressed your concern in a satisfactory way. The question is not a simple one.

SPECIAL ARTICLE

THE SUCCESS OF MEDICARE'S END-STAGE RENAL-DISEASE PROGRAM

The Case for Profits and the Private Marketplace

Edmund G. Lowrie, M.D., and C. L. Hampers, M.D.

Abstract The 92d Congress extended Medicare benefits to patients with end-stage renal disease (ESRD), sparing patients the financial burden of treating this catastrophic illness. The costs of the ESRD program have been contained better than those of health care generally; payment was originally limited by a screen of $138 per dialysis but could be higher if higher cost was documented. About 46 per cent of patients receive dialysis in units outside hospitals. The majority of these units are operated for profit, in which physicians share. The payment to these facilities has remained constant while payment to the nonprofit hospitals' units has increased markedly.

Physicians in for-profit units have a strong incentive to learn about costs and control them. They are involved in medical economic management as well as clinical management; this results in integrated administration of health care. The success of the ESRD program in expanding service to meet demand while controlling costs and maintaining quality has been due primarily to the combined effect of setting a price and creating a system of incentives that involves physicians in the medical marketplace. (N Engl J Med. 1981; 305:434-8.)

LATE in 1972, a complex Medicare-reform bill was amended with a few short sentences to extend coverage to patients with end-stage renal disease (ESRD). There have since been charges of poor planning, cost overruns, profiteering, and program failure; some have cautioned that a new "medical-industrial complex," which could have an adverse effect on medical care, may be emerging.[1] The weight of evidence suggests, however, that these charges are highly inflated if not completely untrue. As we hope to show, the ESRD program has been highly successful in many ways, and there is a strong case to be made for the role of the profit incentive and the private marketplace — not only in the ESRD program but in the delivery of health care generally.

When the financial constraints of treatment were removed for patients, as Congress intended,[2] the population undergoing dialysis changed from an educated, young, white, and male one to a population that better approximates a cross section of American citizens.[3] The number of patients increased, and so did the program's costs. However, one must weigh the financial effect according to both the total costs and the cost of treating an individual patient. Table 1 summarizes these data[2,4] and compares the program's per capita expenditures with other indexes of health-care inflation.[5,6] The cost per patient increased between 1974 and 1979, but when adjusted by the composite or medical Consumer Price Index it actually fell from $14,895 to $13,218 or $12,212, respectively. What has permitted such a remarkable increase in productivity while containing costs better than the medical community has managed to do for health care in general?

A student of the ESRD program,[7,8] Richard Rettig, believes[2] that costs were controlled because payment for outpatient dialysis was limited by a "screen" of $138 per treatment. It is not clear how the screen was selected, but Medicare created cost-containing incentives by placing a cap on the price of service. Hedging a bit, however, the program allowed exceptions if a facility could demonstrate higher costs — regardless of the rates paid to other institutions close by. Rettig[2] also believes that the program's success is due more to the competence of the health-care professionals who provide service than to sound federal policy. If so, why not create a system that provides incentives to the providers of care, making "public use of private interests," as Charles Schultz has suggested?[9] Congress addressed this issue in 1978 by enacting Public Law 95-292, which, among other things, suggested an incentive-based reimbursement system for dialysis by stating,

> Such regulations shall provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services (consistent with quality care) . . . with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of service.

There are three primary participants to whom incentives should be directed: consumers, units, and physicians. However, the policy should focus on controlling the net cost to the public sector, not on advocating one form of medical treatment over another. The concerned parties should be induced to weigh the relative risks, benefits, and costs of competing therapies to make appropriate benefit-cost decisions, but the public should not be forced to pay higher prices for equivalent treatment. Incentives for consumers in general have received attention elsewhere[10-12] and will not be discussed here.

UNITS

The Health Care Financing Administration (HCFA) distinguishes among ESRD units by a four-part classification (Table 2). About one third of the country's 975 dialysis units were located outside hospitals in 1979, and these units were paid $138 per

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Table 1. Costs and Per Capita Expenditures in the End-Stage Renal-Disease (ESRD) Program as Compared with Other Economic Indicators.*

YEAR	AVERAGE ENROLLMENT		COSTS OF THE ESRD PROGRAM			AVERAGE ANNUAL PAYMENTS					
	TOTAL	DIALYSIS	IN CURRENT DOLLARS †	DEFLATED TO 1974 DOLLARS ‡		ESRD BENEFITS PER CAPITA		HEALTH-CARE EXPENDITURES PER CAPITA §		COST PER PATIENT-DAY IN COMMUNITY HOSPITALS ¶	
	no. of patients			*composite*	*medical*	*amount*	*percentage increase*	*amount*	*percentage increase*	*amount*	*percentage increase*
1974	19,000	17,000	$283	$283	$283	$14,895	—	$539.11	11.9	$113.55	10.9
1975	27,000	25,000	450	412	401	16,667	11.9	607.53	12.7	133.81	17.8
1976	35,000	32,000	598	518	487	17,086	2.5	678.79	11.5	152.76	14.2
1977	41,000	39,000	757	616	563	18,463	8.0	768.30	13.2	173.98	13.9
1978	47,000	45,000	947	716	650	20,149	9.1	845.53	10.1	194.34	11.7
1979	56,000	52,000	1,091	740	684	19,482	−3.3	942.94	11.5	217.34	11.9
Average	—	—	—	—	—	—	5.6	—	11.8	—	13.4
5-yr change, 1974–1979 (%)	—	—	—	—	—	—	30.8	—	74.9	—	91.4

*Costs are given in millions of dollars.

†Maintained by the Division of Medicare Cost Estimates, Office of Financial and Actuarial Analysis, Office of Research Demonstration and Statistics, Health Care Financing Administration, Department of Health and Human Services.

‡By setting the Composite or Medical Subindex of the Consumer Price Index for 1974 at 100. From Table 22 of the *Monthly Labor Review*, U.S. Department of Labor, Bureau of Labor Statistics, November 1980.

§National health-care expenditures in 1979 were $212,199,000,000, which represented 9.0% of the Gross National Product, and were distributed over a population of 225,041,000.[7]

¶The average length of stay was about [illegible].7 days, and average gross revenue in 1979 was $249.84 per day.[7]

treatment.[4] Hospital units were paid an average of $159; thus, they received a price subsidy. Some might suppose that because older outpatients with complicated diseases are treated in hospitals, the subsidy is justified. Table 2 summarizes the HCFA's data describing patients undergoing dialysis in early 1980. Patients in hospital dialysis and transplantation units were younger, but the statistical distributions are wide. Such centers often retain patients who will soon receive a transplant, and they tend to be young. Although out-of-hospital units seem to have treated more black patients, one would be hard pressed to find clinically important differences.

About 70 per cent of the out-of-hospital units are run for profit. It may be of value, therefore, to review the economic incentives of for-profit and nonprofit institutions. Profit is defined simply as the amount by which income exceeds expenses. The tax code permits nonprofit institutions to retain these surplus revenues without paying income tax, property tax, or (in most states) sales tax. All others must pay taxes and are profit-making institutions.

The effect of taxes on the net cost of treatment deserves consideration. Assume for the moment that we have two patients requiring exactly the same level of service. One undergoes dialysis in a nonprofit hospital, and the other is treated in a for-profit facility. Since the service required is the same, the cost should be the same — assume $126 per treatment. Assume, also, that both receive the "screen" of $138, leaving $12 in "gross profit." The for-profit facility will return about half this sum in taxes, leaving a net profit

Table 2. Demographic Characteristics of Patients Undergoing Dialysis by Type of Unit.*

CHARACTERISTIC	CENTER (HOSPITAL) †		FACILITY †		OVERALL
	DIALYSIS	DIALYSIS AND TRANSPLANTATION	HOSPITAL	NON-HOSPITAL	
No. of patients	13,591	6984	2500	21,516	44,591
Age (yr) ‡	54.6±16.0	50.7±17.3	54.4±15.5	53.7±15.6	53.5±16.0
Duration of dialysis (yr) ‡	3.1±2.1	3.4±2.4	3.3±2.1	3.3±2.2	3.3±2.2
Female (%)	44.3	43.6	42.7	45.9	44.9
Race (%)					
White	74.1	66.9	75.4	63.9	68.1
Black	22.9	29.2	19.5	33.7	28.9
Other	3.0	3.9	5.1	2.4	3.0
Diagnosis (%) §					
Glomerulonephritis	28.9	29.3	24.9	26.4	27.3
Polycystic kidney disease	9.4	9.1	9.8	8.7	9.1
Interstitial nephritis	9.1	9.7	8.2	8.7	9.0
Hypertension	18.3	15.7	16.6	22.1	19.6
Diabetes	11.5	9.5	9.7	10.8	10.7

*Where percentages are shown, the values indicate the fraction of the patients treated in the type of unit specified who had the indicated characteristic.

†Centers must provide a full spectrum of services, including inpatient dialysis, and must be based in a hospital; facilities may be hospital-based or non-hospital-based.

‡Mean ±S.D.

§The diagnosis was coded on only 23,461 records.

of $6, and the net cost to the public is only $132. The net cost in the nonprofit unit is $138, and the unit effectively receives a $6 tax subsidy. Note that the tax laws provide a method by which "reductions in cost [due to the] more efficient and effective delivery of service" may be shared with the government, as suggested by P.L. 95-292 (see above), and that the effect of any increase in the screen is reduced by the payment of taxes. Recall that in 1979 the payment was $138 to out-of-hospital units but was $159 to hospital units.[4] The premium paid to the nonprofit hospital unit is therefore $27 per treatment. In other words, it receives a dual subsidy: a $21 price subsidy and a $6 tax subsidy. Both are ultimately extracted from the taxpayers. The price subsidy must be met from the Medicare Trust Fund. The tax subsidy is met by higher income, sales, and property taxes, because taxes not paid by consumers of a public service must be paid by someone else. One might argue that the example is contrived (which it is) and that hospitals do have higher costs, so that their profits are not as high as the example suggests. Perhaps, but the reimbursement rates are correct according to the HCFA, and for-profit facilities do pay taxes, thereby reducing net cost.

We may reasonably assume that profit-making centers will seek to maximize profits. Kirsch et al. evaluated patient-selection patterns in for-profit and nonprofit dialysis units for the California State Assembly (Kirsch L. Personal communication), and found no difference in mortality-related risk factors. They found that for-profit units subjected patients to dialysis longer during each treatment, controlling for differences in dialysis equipment and in the initial functional status of the patients. Health economists Held and Pauly analyzed the cost of dialysis in for-profit and nonprofit units for HCFA (Held P. Personal communication), and concluded that they offered the same level of resources (staff, supplies, and so on) per patient. These findings do not support allegations that for-profit units provide less medical service in pursuit of economic gain. It is in the economic interest as well as the professional interest of these units to accept patients and to provide a level of care that is sufficient to maintain health.

By contrast, the economic goals of nonprofit organizations are obscure.[13] Newhouse[14] and Feldstein[15] have postulated that hospitals attempt to maximize the quantity and quality of service within constraints requiring them to "break even." Most economic models, however, ignore the key role of physicians in determining costs.[10] Reder[16] introduced the concept of physicians' prestige. Prestigious institutions attract patients and physicians. Hospitals are therefore induced to expand their inventory of equipment and range of services. Pauly and Redisch[17] view physicians as having de facto control of hospital operations because they control the demand for service in a way that enhances their income. Most models of nonprofit hospitals' behavior assume that they break even — that their profits should be zero. In fact, this is not the case. Davis[18] noted that nonprofit hospitals earned profits during each year from 1961 through 1969 except 1962. Further, data from the American Hospital Association show annual profits in 3330 nongovernmental, nonprofit community hospitals, increasing yearly between 1972 and 1979 from $363 million to $1.7 billion per year (compiled from Tables I and XI of *Hospital Statistics*, 1973 through 1980 editions[4,19]; 792 of the 995 medical-school-affiliated hospitals are included). Expressed as a return on revenue, profits increased from about 2 per cent to 3.5 per cent. Davis[18] also notes that hospitals attempt to maximize cash flow, which is defined as revenue minus operating expenses other than depreciation. They then increase capital expenditures, acquiring the funds from contributions, government grants, and retained earnings. The point of all this is that tax exempt, so-called nonprofit institutions do realize profits, but that their internal motives appear so complex as to defy the explicit understanding of health economists, let alone that of the general public.

One might acknowledge these profits and also accept the notion that nonprofit hospitals with dialysis units receive a dual subsidy, but argue that we must somehow pay for research, education, and similar activities. We support the activities of teaching institutions. Most hospitals are not teaching or research hospitals, however. The typical medical school-hospital complex produces three products: research, education, and health care. It is engaged in joint production, and economic theory[13] suggests that the aggregate, pure production costs should be less than they would be if each product were produced independently. When the pure cost of producing each product is determined, there will remain a residual joint cost that cannot be allocated easily to any one product. The complex, however, receives public funds and private grants to support research, and substantial overhead rates are charged.[20] To protect the public interest, research awards are granted only after careful peer review. The complex also receives public funds to support education, as well as fees from symposiums and courses and payments for health care from public and private sources. Teaching hospitals (and other hospitals) should be paid the market rate for providing health care. Academic institutions should be able to retrieve residual joint costs after reasonable external review, if they are not covered by other sources of revenue. But an unfair, hidden, and unreviewed burden for subsidizing other activities should not be placed on health-care payers (including Medicare), for this avoids the normal review processes that govern the expenditure of public funds. We should not circumvent the right of the public to know and make decisions about the use of public funds by burying the costs of education and research in a health-care-payment system.

PHYSICIANS

A patient who consults a physician hopes that the doctor will decide exactly as the patient would if the patient possessed all the physician's knowledge. Such a perfect convergence is, of course, impossible. The patient does not have the physician's knowledge. The physician is motivated by a variety of considerations, including the patient's self-interest, but is also concerned about fiscal productivity and such competing interests as getting to the office, writing papers, performing research, or simply going home. The trick is to structure incentives so that the interests of physicians and patients converge as much as possible.

Physicians and health-care facilities are related in a highly complex way. Physicians' services account for 18 to 19 per cent of health-care expenditures, whereas hospital costs amount to about 40 per cent.[5,10] Physicians, however, are the decision makers, and they probably control up to 70 per cent of personal health-care expenditures.[10] They have little or no incentive to control the cost of the services they prescribe, and most have no idea of what those costs actually are.[21,22] Any rational system must provide appropriate economic incentives to supplement the strong altruistic motives of those who control the lion's share of health-care costs.

Harris,[23] an economist and physician, has described the strange organizational complexity of hospitals. Essentially, there are two separate but interacting firms: a demand division (the medical staff) and a supply division (the administration). Like Pauly and Redisch,[17] Harris notes that physicians behave in economic ways to ensure that the hospital has an adequate capacity to meet their needs. He concludes:

> Our current regulatory policy toward hospitals is almost exclusively directed at the supply side of the organization. Unless we revise our definition of "hospital" to include the doctor part of the firm, this policy is doomed to failure.[23]

It is necessary, then, to provide physicians with incentives to learn about cost and to reduce it — for example, by giving them a share of the "profit," whether or not the institution is run for profit. This provides incentive to reduce costs; the share of the profit is professional, earned income. Some disdain the notion of providing economic incentive to physicians, believing that it creates conflicts of interest. Such a pristine attitude ignores the simple realities of human behavior. To pretend that physicians do not maintain strong economic interests[10,15] is simply silly. We physicians should not be ashamed to acknowledge that, like others, we consider the financial implications of our behavior as well as the medical and social needs of patients. Others might protest that profit sharing is hidden and differs from fee-for-service payment, which is said to be open. This distinction is also foolish. Potential conflicts exist with the fee-for-service system: e.g., the issue of whether to perform an endoscopy and thus receive a high fee or to forgo it and accept a lower one. The only solution would be to put all physicians on salary and thus eliminate any incentive to increase productivity.[13] With physicians on salary, the incentive would be to reduce work and maximize leisure, because income would be fixed.[13] Although patients are generally ignorant of the subtle but important forces that motivate medical behavior,[10,12,23] they understand the principles of profit. If society can accept the physician's integrity under a fee-for-service system, there should be even less problem with the acknowledged sharing of profits.

About 48 per cent of patients now receive dialysis in out-of-hospital units, which account for one third of all facilities, and most of these units are operated for profit, in which physicians share. The price of treatment in these units has not changed since 1974, remaining at $138 per treatment[5]; this figure represents a 47 per cent decrease when viewed in terms of 1974 dollars. The contribution of profit-making, out-of-hospital units to cost control in the ESRD program, then, cannot be ignored.

CONCLUSIONS

Experience with the ESRD program provides several observations suggesting shifts in policy to stimulate cost control; these shifts may apply to other health services as well. First of all, price subsidies and perhaps tax subsidies for high-cost providers should be eliminated. The success of the ESRD program in controlling costs was due principally to the "screen" and the initial difficulty involved in achieving exceptions to it. Offering price subsidies by making the exception process more lenient can only permit prices to rise. Others have suggested eliminating the special tax status of nonprofit insurers of health care.[24] Such a proposal for providers of health care would meet much political resistance. It is a complex issue that goes beyond the ESRD program, but price subsidies in the program could be eliminated easily.

Secondly, physicians should be encouraged to become involved in the managerial aspects of the medical marketplace. Medical schools have not prepared their students well for this role. Nonetheless, we have the distinct impression that the success of out-of-hospital dialysis units in controlling costs and increasing productivity is due primarily to the sharing of profits by the physicians who are responsible for their management. The "two-company" environment to which Harris[23] refers does not exist. An integrated administration is thus achieved, and the quality of medical care has been preserved, despite (and perhaps because of) the sharing of profits.

Physicians' involvement in the managerial aspects of health care and the provision of health care through facilities that are operated for profit warrant objective and careful evaluation. We should not fear "the new medical-industrial complex."[1] Instead, we should learn to use it to its fullest potential to provide high-quality medical care efficiently.

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STATEMENT OF MR. ROBERT L. GREEN, CHAIRMAN OF THE BOARD, COMMUNITY PSYCHIATRIC CENTERS, SAN FRANCISCO, CALIF.

Mr. GREEN. I am the chairman of a company whose name is Community Psychiatric Centers. Despite the name of the company, 15 percent of our earnings are attributable to a chain of 38 independent dialysis centers. The company is publicly owned, is traded on the New York Stock Exchange. It has voluminous data available to our shareholders, SEC, and others, regarding the cost of treatment. And, likewise, that is true with national medical care. So the difficulty of obtaining data mystifies me. Our records are open to anyone that wants to see them regarding the cost of individual treatment.

In 1981, our company had revenues of $27 million and earnings of about $3.5 million. We did approximately 180,000 treatments. Our costs were approximately $118 per treatment. Now, the data that is used by HCFA is of 38 independent centers. By coincidence, we have 38 centers. HCFA indicates the costs are $108 a treatment; our costs in 1981, actual, $118 approximately, give or take some cents. Now, there is a lag in the data with HCFA. Inflation has persisted, and their figures are from the past. So the adequacy of the data is only fair, and we think our data is as good or better. Moreover, more than half of our facilities are rural, low-wage areas, places such as Rome, Ga.; Sheffield, Ala.; Yuma, Ariz.; Mountain Home, Ark.; Phenix City, Ala.; Greenwood, S.C.; and so forth. We have some 20 centers in rural areas, and we have been aggressively expanding in rural areas and would continue to do so if the program gave us the incentive to do that. Now, I would like someone to think what would have happened to this program if National Medical Care had not, so to speak, invented the free standing center? Where would costs be today if there weren't the good example set by National Medical Care and those like us who have really copied them? Costs would be $275 a treatment. And unless you handicap the horses, so to speak, so you preserve the independent center, you are going to lose that good example. And that is what concerns me the most. So under what circumstances are we willing to stay in the program, so to speak? Our present policy is to do, as you suggest, Senator, is to see how it goes, because we think as the program gains more experience with proposed new rules and the administration is developed, we will understand what the new exception process really means and whether the Government will recognize inflation. Why should the centers assume the burden of inflation? It is stated in this proposal that inflation is not to be reimbursed. Well, that means that we are to shoulder it because the Government does not want to. That does not seem fair to me. I think there should be inflation protection. And so as years go on we will wait and see if the administration sees that argument as sound.

Second, prospective reimbursement sounds good. But what it really is is kind of a ratchet. And that sounds horrible, but if you take a median, you wipe out the top, less efficient group on the first go-around. Then you have got a lower median, and you take another look and you can ratchet it right down until nobody has any profits. Now, our profits in 1981 were 7 percent on revenues and we think that is a reasonable profit in this case. Our profits on assets employed was 11.25 percent. These numbers are not much different than what is earned by Potomac Electric that provides utility services in this area. So we are willing to stay in the program on three conditions. One, that the ratchet is not employed to reduce profits to the point that it is unreasonable. And we think we have reasonable, not outlandish, profits. Second, that there be some inflation protection, and, third, that there be no more than a $4 spread between hospitals and independents. We have tried to compete aggressively with hospitals to get new locations. We don't reject patients. We are willing to take all patients. The attitude that patients in the hospitals are sicker really doesn't wash because we are willing to take the patients that need care, particularly in cases like Mountain Home, Ark., where there aren't too many choices for treatment. Thank you.

Senator **Durenberger**. Thank you very much.

[The prepared statement follows:]

STATEMENT OF ROBERT L. GREEN
Chairman of the Board
Community Psychiatric Centers
before the
Senate Finance Committee
March 15, 1982

Mr. Chairman and members of the Committee, my name is Robert L. Green. I am Chairman of the Board of Community Psychiatric Centers. I appreciate the opportunity to appear today to explain the position of our company regarding the proposed new reimbursement scheme for outpatient dialysis services.

Notwithstanding the company name, Community Psychiatric Center is, I believe, the second largest provider of outpatient dialysis services in the United States. Our company's provision of dialysis services represents approximately 15 percent of our net earnings, and the balance is accounted for by the operation of acute psychiatric hospitals. Although we have a limited stake in the rule-making proceeding, we are concerned that the proposed rates are unreasonably low -- so low as to jeopardize the financial viability of our renal dialysis operations, particularly in rural areas.

In our view, the history of Medicare reimbursement for outpatient dialysis since 1973 has provided a useful lesson. During the past eight years, one group of providers -- the hospital-based facilities -- was paid on a cost reimbursement basis, and costs went up. On the other hand, the costs for the independents, who were paid a fixed rate, went down. The government has logically decided to apply the fixed rate methodology to both hospitals and independent facilities in the future.

This fixed rate reimbursement is called "prospective reimbursement." The government has set the prospective rate at the median cost for all providers with an upward adjustment for hospitals.*/ Such a process is designed to eliminate inefficient providers from the program or to compel greater efficiencies. Once the less efficient providers are forced out of the program or their costs decrease, a second look will show that the median has declined. This would again give the government an opportunity to lower the amount paid to all providers and thereby eliminate a few more in the higher cost bracket. Taken to the extreme, at some point the ratchet cannot be closed any tighter without adversely affecting efficient providers. That's what prospective reimbursement means to me -- the ratchet.

Masochists that we are, we are only willing to play this ratchet game on three conditions:

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*/ The data used to determine the proposed rates are based upon audits made some years ago. It is admitted in the preample to the proposal that these costs have not been adjusted for inflation in the interim. Also, the costs do not include corporate income taxes, which in our case amount to approximately $8.50 per treatment.

Condition One: That we are able to maintain our present profit margins. In 1981 our company provided approximately 180,000 treatments and earned approximately $10.00 per treatment after taxes, a 7 percent after tax margin on revenues. The identifiable assets devoted to our dialysis business cost $16 million. Our return on invested capital ($1.8 million $16 million) is 11.25 percent. The proposal is to lower the $138 screen to $123 in our case.*/ We can absorb some reduction in the cost per treatment, but not the proposed $15 cut. We believe we can save $5 per treatment by greater reuse of dialyzers (although at least one state, Alabama, has adopted a regulation against dialyzer reuse) and stricter staffing controls. Further management initiatives, including possible reduction in employee salaries, might result in additional savings. Our company has a reputation for efficient management of resources. I doubt that other major chain operators have lower labor costs per treatment than our organization. However, reductions in costs in excess of $5 per treatment would be difficult, and reductions in excess of $10 per treatment would be impossible at this time.

Condition Two: That the regulations specifically provide protection against inflation. The proposal states that there will be no specific inflation protection. Given that the $138 rate has been in effect for eight years and inflation in the health field during this period has been substantial, we cannot assure this Committee of our continued participation as renal dialysis providers unless the final regulations include a policy that removes the inflation burden from our shoulders.

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*/ According to the government, the average payment to independents would be $128. Our average is lower, since a majority of our facilities are located in areas where wages are lower than the national average.

Condition Three: That the proposed $4 differential premium paid to hospital-based providers not be increased. Actually, we would have preferred a single rate. Competition spawned the independents as dialysis providers. Logic would indicate that the government, which desires to extend its Medicare dollars to cover more services, would not pay a premium for services provided in a less efficient treatment modality. We can accept the $4 differential because we believe that our efficiency is such that we can continue to be competitive. Any greater differential would, in our view, be unjustified and anticompetitive.

There is one subject that applies more directly to our company than most others. Approximately half of our 38 facilities are in rural areas; many are sole providers in isolated areas. As I understand the proposal, an exception to the rates would be granted only if we are losing money in any of these locations, and only to the extent that the revised rate would allow us to break even. It is difficult to operate dialysis facilities in remote locations, and we must have a financial incentive to do so. Therefore, I respectfully submit that the exception process must provide for a reasonable return on investment.

Thus, Mr. Chairman, the fixed rate prospective reimbursement methodology is acceptable to our company. With a few minor exceptions, I believe HHS has done a superb job of analyzing the issues and making a workable proposal under difficult circumstances. However, the prospective reimbursement ratchet must be tailored to enable independent facilities, such as ours, to realize a reasonable profit. Our company's policy is to remain in the dialysis business if we can maintain our present profit margins which we believe are reasonable. We can only achieve this if HHS increases the rates by at least $5 per treatment and provides inflation protection for the long term.

In summary, Mr. Chairman, we are enormously concerned over the impact of the proposed rates on our ability to continue to provide dialysis services. We do not intend to close facilities if those rates are ultimately adopted. This service is a life-saving procedure, and we take our responsibilities seriously. However, unless the modest changes I have suggested are made, we would gradually withdraw from the dialysis business, turning the operation of our facilities over to those who can continue to provide the services. However, at this point, no one knows whether there would be any such organizations. We submit that the short-term costs of maintaining a stable delivery system are small compared to economic and social costs that would result from any significant withdrawal of capital from the independent dialysis industry. Obviously, our industry and this Congress have no interest in seeing the disruptions in patient care that would result from any substantial reduction in the availability of dialysis services.

Mr. Chairman, this concludes my statement, I will be pleased to respond to questions.

STATEMENT OF MS. JULIANA WEIDIG, CO-OWNER AND ADMINISTRATOR, SHADY GROVE DIALYSIS CENTER, GAITHERSBURG, MD.

Ms. **Weidig**. Mr. Chairman, I am Juliana Weidig, administrator for Shady Grove Dialysis Center, and with me is Jeannette LaChat, our head nurse. We want to thank you for this opportunity to appear here and discuss with you what we feel is most crucial to home hemodialysis. We are a small center, located in Rockville, Md., and began operation in March 1980. We care and are dedicated to home hemodialysis. That is how and why our center was created, to offer patients an independent and high quality alternative which is also cost effective for the Government. The reason our center is so successful—and 35 to 40 percent of our patients are home-trained—is not only because of our philosophy and committed staff—that is only half the ingredients—but also because of the 100 percent reimbursement agreement and target rate. Both halves are equally important. You cannot have one without the other. We believe HCFA's goal in the newly proposed regulations was to, first, promote home dialysis, and, second, to streamline the program. We agree with their goals. Unfortunately, in eliminating the 100 percent reimbursement agreement, HCFA has negated their goal to encourage home dialysis. We think no one was truly aware of the significance of the 100 percent reimbursement agreement, since so few centers are participating at this time. In our written statement we outline the cost of supportive equipment needed to send a patient home. This cost is about $12,000. No center can absorb this initial cost of sending a patient home. Without the 100 percent reimbursement agreement, home dialysis will come to an abrupt halt. Thank you.

Senator **Durenberger**. Thank you very much for your testimony.

[The prepared statement, question, and answer follow:]

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Jeannette LaChat, B.S.N.
Head Nurse

March 12, 1982

Mr. Chairman and Members of the Subcommittee:

The proposed new regulations for the end stage renal disease program will, enacted as they stand, be a total disincentive for our home hemodialysis. Unfortunately, the debate that has come forth in the media as well as in the committee hearings has focused on the reimbursement rates for in-center dialysis and on the rates for dialysis in the hospital. However, the most blatant and serious problem of these regulations is not the fact that these reimbursement rates are being lowered slightly, but that these regulations will kill any incentive for home hemodialysis. The fact that 100% reimbursement rate will be done away with will result in the total loss of any incentive for any center to put patients at home.

We at Shady Grove Dialysis Center are a small facility that is dedicated to home hemodialysis and under the present regulations, using the 100% reimbursement rate and target rate, we have managed to put 17 patients at home in the last two years. The initial cost of placing someone at home is a capital outlay of somewhere between $11,000 and $12,000. This capital outlay does not just involve one machine and one company. It involves purchasing a dialysis machine (approximately $7250), a mini reverse osmosis unit (approximately $2500 -- $3500), a reclining vinyl chair (approximately $300), installation of electrical ground fault (approximately $160), and miscellaneous items, such as; blood pressure cuff, detecto scale, dialysate meter, tubing clamps, etc. (approximately $524). All of these items are from different companies and are necessary supportive equipment that must be brought and placed in the patient's home. Without the 100% reimbursement program, it will be virtually impossible for any company or dialysis unit to absorb this capital outlay with the proposed new regulations. The result of this will be that home hemodialysis will be stifled. The only form of dialysis that will occur will be CAPD, which has an application limited to a maximum of 20% of the dialysis population. Thus, if the intent of Congress is to encourage home hemodialysis, under the proposed regulations, they will do just the opposite. If the dialysis units were required to pay the cost of the supportive equipment needed for home dialysis under current interest rates of 18-18½%, a 3 year payout would add an additional cost of $45.00 per dialysis treatment. For a 5 year payout, the additional cost per dialysis treatment would be $40.00. Any lease agreement would increase this cost per dialysis treatment to perhaps as high as $50.00 per treatment. The hidden risks in this program would be amounting indebtedness of the dialysis unit in the face of uncertain and fluctuating interest rates and the risk of equipment that remains idle, while payments must continue with no ability to pass these risks or costs on to the consumer of services or Medicare.

We strongly feel that the regulations should be written to allow patients to have the widest possible freedom of choice of modality. Under the proposed regulations, patients only have two choices -- in-center dialysis and CAPD. Home hemodialysis will be impossible to be obtained. We would rather see a lowered rate for dialysis in the home and maintain the 100% reimbursement agreement.

Question. Given an initial equipment and installation cost of $12,000, an interest rate of 18 percent, and a 3-year payback period, it would cost $33.37 per treatment to place someone on home dialysis. That leaves about $95 to cover all other costs. For a 5-year payout period, the per treatment cost is about $24. In light of this information, do you believe non-profit and small independent facilities can finance the dialysis equipment and installation needed to initiate a new home dialysis patient if the 100 percent reimbursement mechanism is eliminated?

Answer. In answer to your question dialysis centers will be unable to send patients home on dialysis under the newly proposed regulations. The reasons for this are as follows:

(1) You cannot estimate 156 dialyses per yer per patient. 138 dialyses per year per patient is more reasonable in order to account for hospitalizations, travel, machine breakdown and patients who dialyze two times a week (104/yr.).

(2) Machine maintenance and part replacement costs approximately $1,000 per machine per year.

(3) Machines that remain idle, due to patients that have been transplanted, hospitalized or are deceased, would still require monthly installment payments.

Using the above assumptions, a $12,000 cost for the initial home equipment amortized for 5 years at 18 percent interest with an additional $80 per month for maintenance and 138 dialyses per year per patient yields a cost per dialysis of $40.00 and does not account for machines that are unused.

STATEMENT OF DWIGHT GEDULDIG, ACTING DIRECTOR, WASHINGTON, D.C. OFFICE, AMERICAN HOSPITAL ASSOCIATION, CHICAGO, ILL.

Mr. **Geduldig**. Thank you, Mr. Chairman. I am Dwight Geduldig, acting director of the Washington Office of the American Hospital Association. I appreciate the opportunity to appear before the committee. I have recorded a summary of my remarks at 33 and I will play them back at 78. And, briefly, I would like to touch on several points that were made today and reemphasize if nothing else. We are sympathetic, of course, with the renal dialysis units in the hospitals and that the Government gets its biggest bang for its health care dollar. We take exception to the departments labeling of hospital dialysis units as inefficient when there is no data extant for that. We take exception to the proposed data methodology because we think it was all done with mirrors and it is Alice in Wonderland. We request that it be redone. We are pleased that hospitals are leading the way for home dialysis without any incentives such as is proposed in the rates, whether they are right or wrong.

We only have a handful of anectodal data on hospital costs, and I will not refer to those because considerable data has been offered, whether I think it is valid or not. I will go on to the final point. We are offering to work with the department on incentives, on one side, and we are encouraging our hospital units and furnishing dialysis to justify their costs during this comment period. Thank you.

Senator **Durenberger**. Is that it?

Mr. **Geduldig**. That's it.

Senator **Durenberger**. I appreciate that. I take it you have a full statement which will be made part of the record, whether it is a recording or not.

[The prepared statement, question and answer follow:]

AMERICAN HOSPITAL ASSOCIATION
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WASHINGTON OFFICE

STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION
BEFORE THE
COMMITTEE ON FINANCE
UNITED STATES SENATE
ON PROPOSED MEDICARE REGULATIONS
FOR OUTPATIENT RENAL DIALYSIS SERVICES

March 15, 1982

Mr. Chairman, I am Dwight M. Geduldig, acting director of the American Hospital Association's Washington Office. On behalf of our more than 6,100 institutional members and 30,000 personal members, I appreciate this opportunity to comment on the operation of the Medicare End Stage Renal Disease (ESRD) program and the Health Care Financing Administration's (HCFA) proposed regulation establishing a new prospective payment rate for outpatient dialysis services.

The ESRD program has attracted considerable attention, largely bacause of its growth and impact on Medicare costs. Approximately 654 hospitals provide outpatient renal dialysis services. HCFA data indicate that when the program started in 1974, 11,000 patients received ESRD services under Medicare at a cost of approximately $229 million, a yearly cost of $20,800 per patient. In 1981, 68,200 ESRD patients cost Medicare approximately $1.5 billion, a yearly cost of $22,000 per patient. Thus, while the number of patients increased more than sixfold in seven years, the cost per patient treated has increased only 5.8 percent.

CABLE ADDRESS AMERHOSP

Despite the reason for program growth--patient demand--HCFA's proposed regulation of February 12, 1982 seeks reductions in total ESRD outlays rather than addresses the problem's cause--the drastic increase in the number of patients receiving benefits. We find this rationale faulty since it ignores the primary reason for escalating program costs. We doubt the regulations will achieve the mandated objective of significantly reducing program costs through incentives for home (self) dialysis.

Rising program costs motivated Congress in 1978 to require the formulation of a reimbursement structure which would encourage cost efficient delivery of dialysis services while ensuring quality care and accessibility of services. Last year, as a follow-up, Congress enacted legislation (Section 2145, P.L.97-35) directing the HHS Secretary to develop a composite rate structure which would encourage all facilities to increase utilization of less costly home dialysis services. In addition, Congress required that "separate composite weighted formulae" be calculated for hospital-based and for other renal dialysis facilities. This Congressionally mandated, dual rate structure came soon after HCFA had proposed a single prospective rate based only on the median costs of nonhospital facilities. AHA applauds Congress for its insistence on a dual rate structure which recognizes legitimate differences between costs in hospital-based facilities and costs in facilities not related to hospitals.

AHA believes that the prospective payment rates should encourage selection of the least costly appropriate form of treatment for each patient. These rates, however, also must be adequate to ensure that all levels of treatment will be available. There may be some patients currently being treated in hospital-based outpatient facilities who can safely be moved to less costly settings. However, there is a group of patients, unfortunately not yet clearly categorized, who must be treated in the hospital-based setting and will have to be treated there in the future. Our focus is to review the adequacy of the proposed rates for service to those patients who, because of medical, psychological, or simply logistical reasons are unsuited for home dialysis and therefore must be treated in a facility.

Accessibility is the key element of the ESRD program--dialysis services must be available to all who suffer from end stage kidney disease or they will die. Improper rates could impede delivery of the most appropriate level of care.

The House Ways and Means Committee report accompanying Section 2145 noted "that since enactment of the (renal) Amendments of 1978, there has been a modest increase in the number of end stage renal disease (ESRD) patients self-dialyzing at home." Further, the Committee notes that "a substantially greater number of renal patients could be dialyzed in the home setting...." Also, "the Committee recognized that not all patients are medically appropriate candidates for home dialysis...." Home dialysis requires a great deal of patient education and compliance as well as a stable, reassuring home environment.

HCFA Policy Bias

HCFA's proposed incentive payment rule presupposes that the number of renal patients potentially able to dialyze at home "could approach 30 to 40 percent within five to seven years." If this is a valid target, then hospital-based facilities already have achieved considerable progress in meeting it because HCFA data reveal 23.5 percent, or almost one out of four hospital-based patients, are on self-dialysis.

In an internal memorandum, HCFA acknowledges that the rates are on average set below current payment rates," and that the agency's prime motivation in selecting its methodology was to get as close to a single rate as possible. HCFA states in the memo that one of the major advantages of its methodology is the provision of "flexibility to revise the adjustment for hospital-based facilities in later years and perhaps phase it out altogether." The document also states that the methodology "minimizes the differential between hospital-based and indepedent rates." Such statements reveal that HCFA is predisposed toward a single rate structure and in fact has developed a structure that can be adjusted easily to meet that goal.

HCFA PROPOSAL

Having expressed our concerns with HCFA's failure to address the overriding problem of ESRD program growth and our feeling that the proposed regulations are not fully responsive to the intent of Congress when it passed Section 2145 of the Omnibus Reconciliation Act of 1981, we now identify specific concerns relating to HCFA's development of new prospective payment rates. Those concerns have to do with the inadequacies of the data used to arrive at the prospective rates, the rate-setting methodology itself, and the exceptions process outlined in the proposal.

HCFA's proposal does, however, correctly identify a problem with the current law that discourages the statutory objective of increased home dialysis. This is a valid point. The law permits home dialysis patients to bill the program directly for supplies and equipment rather than bill through the facility. Currently, many home dialysis patients use the direct billing option. Since there is nothing to discourage the continuation of this practice, the theoretical incentive which the composite rate gives facilities to move patients from in-facility dialysis to home dialysis is virtually eliminated.

Data Base

The data used to develop the rules and composite rates for outpatient dialysis are incomplete, and by HCFA's own admission, subject to criticism. The Inspector General and General Accounting Office have also raised concerns about the adequacy and completeness of the data, and questioned the usefulness of the data as a basis for developing reasonable and reliable rates.

The House Ways and Means Committee report accompanying Section 2145 assumed that "adequate cost data should be available on which to establish costs for the home dialysis component of the composite rate" because the Medicare program has been paying for this service since 1973. To the contrary, evidence shows the data base is extremely weak and deficient. Also, AHA is very concerned that no patient mix data are available to reflect differences in intensity and resources of different types of dialysis providers. Without this type of data, rate setting is simply arbitrary.

Moreover, there are apparent disagreements among HCFA staff over what the available data actually show. Representative L.H. Fountain, chairman of the Government Operations Subcommittee on Intergovernmental Relations and Human Resources, during a recent hearing on the administration and management of the ESRD program, entered into the record a February 22 document prepared by staff of HCFA's Office of Research, Demonstration and Statistics which states that, "there may be differences in patient mix between freestanding and hospital-based facilities which could impact on the costs of providing services to the ESRD population." The HCFA staff, while acknowledging a lack of conclusive evidence, notes "the fact that hospitalization rates are higher for hospital-based facility patients could be related to greater need levels...." HCFA thus made policy decisions without collecting relevant patient data.

Cost Data

Although the statute mandates dual rates, HCFA is using a median cost value for all providers and is simply making several arbitrary adjustments in developing different rates applicable to hospital-based and other renal providers. This approach provides only a minimal adjustment for hospitalbased services.

In fact, the internal HCFA memorandum we refer to earlier clearly identifies the approaches taken by HCFA to arrive at its proposed rates. The memorandum notes the intent of Congress to have HCFA develop a dual rate structure but also notes that compliance with truly dual rates "reduces potential program savings."

We believe it is extremely important for this committee to review the rationale used by HCFA in developing proposed dialysis rates. HCFA acknowledges in the memorandum that "the cost of furnishing dialysis varies widely. Some facilities re-use dialyzers, make greater use of paramedical or nonprofessional personnel, or have lower staff-to-patient ratios. We (HCFA) do not know at this point what the optimum combinations are and how the cost of dialysis correlates to these variables. For example, we (HCFA) do not know whether as many patients of high cost facilities actually require as high a level of care as indicated by the costs. Nor do we (HCFA) know the extent to which patients participate actively in their own care in order to reduce labor costs."

Thus, the proposed cost bases do not reflect the legitimate cost differences among renal dialysis providers. Rather, "in the absence of a definitive standard for an efficiently and economically operated facility," HCFA is relying solely on a median cost determination. Yet, HCFA has acknowledged cost differences between hospital-based facilities and other renal providers for labor, overhead, and supplies. However, no attempt has been made by HCFA to fully explain why these differences exist or to develop the data which will either substantiate or refute hospital-based dialysis costs levels.

For example, HCFA contends that all dialysis providers should incur the same costs for supplies and, therefore, discounts as irrelevant the fact that hospital-based facilities' supply costs are $4 higher on a per treatment basis than the supply costs of other facilities. Nevertheless, HCFA acknowledges hospital-based programs are on average considerably smaller than independent facilities, and that the wide dispersion of hospital-based units results in higher transportation costs. Economies of scale have not been adequately evaluated.

Other factors also bear directly on costs. For example, under Medicare and state laws, hospitals must meet stringent life safety and staffing codes, therefore incurring higher operating costs than do freestanding facilities. In the ESRD network many hospitals serve as back-up to independent facilities for more serious cases. These responsibilities lead to hospital labor costs that are $20 per treatment higher than labor costs in independent facilities. HCFA did not collect data on these factors and has chosen not to make any adjustments for them.

Therefore, we believe it is highly inappropriate to make critical assumptions in developing a reasonable cost base without thoroughly researching why these cost differences exist.

Composite Rate Formulas

The weighting factor used by HCFA in its hospital-based composite rate formula may be overstated and may be a disincentive for hospitals to transfer additional patients into the home dialysis mode.

HCFA acknowledges in the decision memorandum that an inconsistency exists. We urge that Congress evaluate the appropriateness of the HCFA weighting factor. It should be apparent that future increases in proportional home dialysis services are unlikely because the proposed formulation penalizes the shift towards more cost-efficient delivery.

Exceptions Process

In lieu of having accurate cost and other data, HCFA has included, as required by Congress, an exceptions process. This process is intended to provide relief from the proposed rates if valid reasons exist.

Since so little aggregate data are available on the program, generally an individual hospital will find it difficult to demonstrate its justification for an exception. In fact, HCFA states that it expects to grant few exceptions. We find this unacceptable and contrary to Congressional intent which calls for a process to recognize "the added costs of facilities, usually hospitals, whose dialysis services are largely geared to less stabilized, more costly patients...."

Rate Adjustment

HCFA plans to use a 5 percent adjustment factor for hospital-based facilities because "any deficiencies in the (HCFA) data would impact the hospital-based facilities more than independent facilities. In addition, the use of the composite rate has a greater immediate effect on the hospital-based facilities, because the percentage of home dialysis patients is greater for hospitals than for independents."

HCFA Administrator Dr. Carolyne Davis told the House Government Operations Committee's Intergovernmental Subcommittee that the 5 percent factor was chosen instead of 10 or 20 percent in the interest of cost savings. According to Dr. Davis' testimony, the 5 percent adjustment figure is intended to account for:

- the possibility that the methodology used may have failed to recognize fully the legitimate cost of hospital-based facilities,
- any shortcomings in the audited data,
- age of the data, and
- the hospital-based labor component used in computation which adversely affects hospitals because the percentage of home dialysis patients is greater for hospitals than for freestanding facilities.

Thus, HCFA acknowledges that its rate methodology may be defective and does not properly recognize costs incurred by hospitals. It is clear from Dr. Davis' statement before the Intergovernmental Subcommittee that the 5 percent adjustment is purely arbitrary and that HCFA had no rational basis for determining the level. Rather, HCFA's motivation was solely to reduce costs and the adjustment is a token to partially offset shortfalls.

Even so, the proposed rule states that the rates will result in reimbursing 46 percent of all hospital-based and 28 percent of all independent facilities at a rate per treatment below their current costs for in-facility dialysis. This will confront hospitals with a difficult choice: whether to continue providing outpatient dialysis in the face of payment shortfalls or to discontinue a this vital service.

SUMMARY

AHA is concerned with the growing cost of the end stage renal disease program and its impact on the Medicare costs. However, we believe most of the growing costs are not caused by inefficient and high-cost providers. Rather, we believe the major factor behind the program's growth is the steadily increasing number of patients. The per treatment cost is not a significant factor in program growth. AHA supports development of an appropriate policy to promote home dialysis.

AHA believes HCFA's proposed prospective payment rates are based on incomplete and suspect data. HCFA itself has admitted serious problems in that regard. As a result, the rates are inaccurate and do not even approximate the cost of providing outpatient renal services.

AHA wishes to emphasize that hospitals already have 23.5 percent of their patients on home dialysis. That represents two-thirds of HCFA's goal of achieving a 30 to 40 percent nationwide figure in the next five to seven years. We are concerned that the weighted composite rate may provide a negative rather than positive incentive to continue this trend.

We believe the proposed exceptions process is impractical. Only minimal relief can be expected because the burden of proof lies on the provider, and there are no data presently available to assist providers in presenting their arguments.

AHA finds unacceptable the fact that the proposed rates will adversely affect 46 percent of all hospital-based programs.

AHA Recommendation

AHA recommends that Congress require HHS to suspend its proposed rulemaking of February 12. We believe Congress should require HHS to perform a study within the next six months to yield the data necessary, including a patient-mix analysis, to develop a dual rate system that accurately reflects the costs of providing this lifesaving service. AHA would like to work with HCFA to design such a study.

We believe HCFA should not be permitted to implement prospective rates until such time as this study is completed. This restriction would result in a positive incentive for HCFA to perform the study quickly.

Question. Is is possible, as has been suggested, that hospitals finance part of the cost of acute inpatient care by shifting costs to cost centers with high medicare utilization rates—the renal dialysis cost center being a likely candidate for such shifting?

Answer. Hospital costs are generally characterized as direct or indirect. Direct costs are those such as salaries, supplies and equipment which are associated and identified with a specific revenue producing department; such as the renal dialysis cost center. Indirect costs (overhead) are costs incurred in operating a hospital and which are allocated to revenue producing departments, using various statistical measures. These departments include: hospital administration, accounting, housekeeping, dietary and so forth. Medicare regulations (42 CFR 405.452 and HIM-15) detail very specifically how this cost allocation process operates. A majority of a renal dialysis center's costs are direct.

Medicare cost allocation rules distort the allocation of indirect costs, causing cost shifting. AHA believes that Medicare rules therefore produce a distortion between inpatient and outpatient costs, with the outpatient area receiving a greater proportion, and conversely the inpatient a lesser proportion.

However, it should be recognized that Medicare payment in aggregate for inpatient and outpatient services reflect the amounts recognized by the program as allowable and reasonable.

STATEMENT OF DR. HERSCHEL HARTER, MEDICAL DIRECTOR, CHROMALLOY AMERICAN KIDNEY CENTER, ST. LOUIS, MO.

Dr. HARTER. Senator, may I make one comment?

Senator DURENBERGER. Yes.

Dr. HARTER. I am Dr. Herschel Harter. I am the medical director and director of the Chromalloy Kidney Center, which was added on a bit late. And I will make a 5-minute dissertation in about 30 seconds.

A couple of points. We are a hospital in-center facility that operates on free-standing rates, so proper adjustment can be done. Second, we have been dedicated to home dialysis—we are in the middle of the United States—and we have approximately 88 percent 3-year survival at home, and a 75 percent in-center survival, despite an indigent, often black population. But there is another problem with the regulations that I think needs to be brought to your attention, and that is that for the first time at least, besides instituting health care support, the Government has opted to support a process that, in my own mind—at least with our own research—may not be the optimal form of therapy and that is CAPD. You have historic information on home dialysis, and you have historic information on in-center dialysis, which have very good long-term results, some better than others. The data that we have and that other centers in this country have on CAPD make it, I think, less likely to be a viable long-term home treatment mode. We have a 40 percent 3-year dropout. It has been seen in Iowa, Mississippi and in Europe. And in my statements which you have, you have all the data on that.

Furthermore, it bothers me a bit that it is a rather monopolized type of therapy. And in that respect, I think competition will help bring the cost on, because as it is now, it is not a cost effective method for home treatment. It is much more expensive than home hemo, at least in our hands. Plus the fact that the companies involved with this have I think had a large consulting service which really limits advances in the field of CAPD. So I would hope that you look carefully at that data, because to push that kind of treatment, I mean, after 3 years, and they come off of CAPD, and we have limited reimbursement rates, what do we do with those patients? I mean, we are stuck with them. Thank you for your time.

Senator **Durenberger**. Thank you very much.

[The prepared statement follows:]

WASHINGTON UNIVERSITY
SCHOOL OF MEDICINE

HERSCHEL HARTER, M. D.
MEDICAL DIRECTOR
CHROMALLOY AMERICAN KIDNEY CENTER
4949 BARNES HOSPITAL PLAZA
ST. LOUIS, MISSOURI 63110

March 9, 1982

Mr. Robert E. Lighthizer
Chief Counsel
Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lighthizer:

I am writing this statement because of your request for responses to the proposed new reimbursement rates for ESRD facilities. I am an Associate Professor of Medicine and Director of the Chromalloy American Kidney Center of Washington University School of Medicine in St. Louis, Missouri. This kidney center, which was started in 1966, is operated by Washington University as an academic institution which is located in the Barnes Hospital Complex. This facility provides services to much of the inner city residents of St. Louis. As such, our population is older, black and often indigent. Our facility, has provided quality care for this population despite charging a free-standing reimbursement rate rather than an in-hospital rate. Because of the nature of the population, certain excess support services are required including: 1) funds for transportation, medication, heating and the like, 2) rehabilitation and occupational services to insure that those patients capable of returning to gainful employment do so, and 3) added social work and dietary services to insure proper compliance and potentially long-term survival of our population. It must be remembered that many of these indigent patients are not eligible for Medicare coverage of dialysis charges. As such, the costs for this treatment must be born by the states or the facility itself. It is our policy to provide dialytic services regardless of the financial conditions of the patient. Recently, because of budgetary constraints, the reimbursement policies of both Missouri and Illinois have been reduced. In fact, Illinois has not reimbursed our facility for over six months for dialysis services. Approximately 25 patients are involved. Obviously, therefore we provide this service at no charge to the patient.

The Chromalloy American Kidney Center has been dedicated to the concept of home hemodialysis. Until 1974 approximately 60% of all patients accepted to our dialysis program became home hemodialysis patients. This program was very successful and 80' of the first 100 patients so treated survived for six years or longer. These patients were carefully selected and criteria such as age, family support, absence of complicating medical illnesses and the like were carefully considered before patients were accepted for chronic dialytic care. In 1972, P.L. #92-603 was passed and the law implemented in 1973 extended Medicare coverage to all patients with end stage renal disease as long as Social Security eligibility requirements were met. This meant that the selection criteria that were once used were no longer appropriate and patients of all ages, regardless of complicating medical illnesses were accepted. At the present time, only about 22% of our population is receiving treatment at home, including home hemodialysis and chronic ambulatory peritoneal dialysis (CAPD). Since about fifty patients are transplanted from our unit every year, all under age 55, we now have a large center hemodialysis population with a mean age of 55. Many of these patients have complicating medical illnesses such as diabetes mellitus. Furthermore, a large number of these patients have been successfully treated for 10 years or longer. You must keep in mind the fact that the ideal home hemodialysis or CAPD candidate is also the ideal transplant candidate. Thus, centers such as ours, which transplant a large number of their younger, more stable patients, will have fewer candidates available for home dialysis therapy.

At a time when costs are escalating, especially wages, support services, costs of dialyzers and other necessary dialysis software, the government wishes to reduce the reimbursement rate, despite the fact that this rate has been constant for over seven years. The proposed regulations will reduce funding for center hemodialysis by 12%. What does a dialysis center such as ours which transplants the majority of patients under age 55 and sends to home dialytic care another 22 percent of the population do? The average age of the remaining patients is over 55 and many of them have complicating medical illnesses or lack of family support such that home dialysis is not feasible. The methodology for rate setting does not seem appropriate. Our nurse salaries have increased approximately 32 percent since October of 1980. We must use only registered nurses in our dialysis facility since Missouri law prohibits licensed practical nurses or dialysis technicians from performing venapuncture, initiating or discontinuing hemodialysis or giving intravenous solutions to dialysis patients. All units in Missouri utilizing LPN's or technicians as part of the hemodialysis staff have been cited by the Missouri Division of Health as noncompliant. These positions must be filled by registered nurses within a six-month period of time. It does not seem feasible that this facility will be able to adapt to these new rates. Obviously, if we are required to provide dialysis care at the projected rates we will need to increase significantly our patient-nurse ratio. It is clear, therefore, that the more aged or medically unstable patient will be more difficult to treat under these circumstances if at all.

The End Stage Renal Disease programs (Networks) were established by The federal government to provide a mechanism to insure adequacy of care and potential needs for hemodialysis units. These Networks have stated that all patients have the right to receive information about, access to and freedom to select the treatment modality of their choice. This choice is made after each treatment modality, including benefits and disadvantages, have been presented to the patient. The proposed regulations (pages 6567 and 6568) of February 12, 1982, advocate the increased use of CAPD as the treatment of choice for many patients. It would be interesting to know what information the authors have used to make this recommendation. CAPD has not been a cost effective form of home dialytic treatment. Until very recently there was only one manufacturer of the dialysis solutions. That manufacturer has essentially had a monopoly in this field and furthermore has engaged fifty or more nephrologists from the largest CAPD programs in this country in restrictive consultatory agreements. Furthermore, when it appeared that the Composite Rate Reimbursement Regulations would be passed and CAPD promoted, the prices for CAPD products increased by 40 percent.

There is also increasing evidence that there are many medical problems associated with CAPD. CAPD was started in 1979 and is still a relatively new form of treatment. Recent publications from several centers world-wide (see enclosure), would indicate that there is a very high turnover rate in this population, and that the treatment should be prescribed with caution. Forty-three percent of the patients treated with CAPD at the Chromalloy American Kidney Center have been withdrawn from that treatment modality within 36 months of its initiation. The majority of the patients died or returned to hemodialysis. Forty-seven percent of the CAPD patients in Iowa were also removed within 41 months (see enclosures). Similar observations were seen in New Jersey, Michigan, Australia and England. It is suggested by these reports that careful attention to patient selection for this treatment modality be assured. This is a world-wide observation that must be documented before the federal government makes suggestions regarding the forms of chronic dialytic care. Many researchers in this field have suggested that between 12 and 20 percent of the patients with end stage renal disease could be treated with this modality. What do we do with the remaining population? What do we do with the patients who have been unsuccessfully treated with CAPD?

In summary, it seems unreasonable to me to expect that the new reimbursement rates will be feasible. They were based on old information which must be updated. Because of the nature of the incenter dialysis population in many dialysis facilities, this rate will not be adequate to insure dialytic care for all patients. Those most likely to be affected include the elderly, medically unstable and indigent populations. I fully agree that home hemodialysis is a viable treatment modality that should be actively pursued. On the other hand, to encourage patients to be treated with CAPD, which is very expensive and potentially dangerous, seems totally unjustified to me.

Sincerely,

Herschel R. Harter, MD

Herschel R. Harter, M.D.
Associate Professor of Medicine

HRH/bl
Enc.

STATEMENT OF G. MARSHALL ABBEY, VICE PRESIDENT, BAXTER TRAVENOL LABORATORIES, INC., DEERFIELD, ILL.

Mr. ABBEY. Mr. Chairman, I am Marshall Abbey. I am a vice president of Travenol Laboratories. Appearing with me today is Dr. James Winchester, a nephrologist and assistant professor of medicine at Georgetown University Medical School. At the conclusion of my short comments, he would be glad to answer any medical questions the committee might have, particularly in reference to CAPD.

Travenol is a leading manufacturer of disposable dialyzers and dialysis supplies, both for hemodialysis and the newer treatment modality, CAPD. Because of our role in the industry, whatever happens in that industry is of interest to us and, therefore, I welcome the opportunity to be here today.

With minor exceptions, Travenol endorses the proposed regulation issued by HCFA and compliments HCFA on its studied approach and careful attention to congressional intent.

Most of the criticism which has surfaced on the regulations seem to deal with whether $132, $128, or some other figure is the appropriate rate. Travenol takes no position on this issue, but does urge that the base rates be set so as to keep hospital centers in operation. As I will comment in a moment, the hospitals have been more active in encouraging the use of the lower cost home dialysis.

My major purpose in being here today is to make sure that the subcommittee appreciates the importance and the significance of the composite nature of the proposed rate. Composite means that the reimbursement will be the same regardless of the treatment modality and regardless of whether the patient is treated in the center or treated at home and monitored by the center. Since home dialysis, whether it be hemodialysis or CAPD, is lower cost than in-center dialysis, the composite nature of the rate will incentivize home dialysis and lower program costs.

To pursue that example for one moment, if the in-center, whether it is hospital or freestanding center, costs are here and the home costs are here, the composite rate can be set somewhere in between those, and by varying the mix of patients treated in the center or at home, the facility cannot only recover its cost but make whatever profit it thinks is appropriate.

There has been much comment earlier about the extent to which home dialysis is utilized or underutilized in the United States today. I will not add to that, except I think statistics have shown that consistent with current standards of medical appropriateness, the percentage of patients on home dialysis can be much higher than the 18 percent which is in effect in the United States today.

I think, Senator, in giving you some statistics in other States, we neglected to mention that in the State of Minnesota it appears that the current percentage is 32 percent on home dialysis.

Of particular interest to this subcommittee I think should be the identification of the types of centers which send patients home. On the basis of a Travenol survey, which is quite consistent with Dr. Davis' survey, we learned that hospital centers which have 54 percent of all the kidney patients in the United States monitor 70 percent of the home patients. Freestanding centers which treat or monitor 46 percent of all kidney patients monitor only 30 percent of all home patients. To put it another way, hospitals send approximately 24 percent of their patients home; freestanding centers send approximately half of that amount. The goal of the Government, the patients and the dialysis industry should be to reduce costs. A composite rate will result in increased use of home dialysis and will help us attain that goal. Thank you.

Senator **Durenberger**. Thank you very much. And I would thank you all. I would suggest that it is appropriate for all of you, if you so desire, to add or elaborate on your testimony in any way on the basis of what suggested by others during the course of the day today. We should not judge the interest in this subject on this committee by the number of people who were able to attend today. Monday is not the best day to get Senators to come to hearings. There is a strong interest for the reasons that I indicated earlier. I am sure this committee would have difficulty on the basis of the testimony today coming to a conclusion on the appropriateness of the dollar amount set in the regulation and for a lot other reasons that were talked about here today. But just as important as that, of course, is the direction in which we try, with your help, to move the system. And so to the extent that there are contradictions here that appear that might be cleared up, data bases that appear to some to be clearly erroneous which you want to clear up, I would suggest it is very appropriate that you add to the testimony that you gave today in any way that you think is appropriate and it will be made part of this record. Thank you all very much for being here today. And the hearing will come to a conclusion. Thank you.

[Whereupon, at 12:31 p.m., the hearing was concluded.]

[By direction of the chairman the following communications were made a part of the hearing record:]

TRAVENOL LABORATORIES, INC.

One Baxter Parkway Deerfield, Illinois 60015

STATEMENT

on

Renal Dialysis Reimbursement Issues

before the

Subcommittee on Health,
Committee on Finance
United States Senate
The Honorable David Durenberger, Chairman

presented by

G. Marshall Abbey
Vice President

Washington, D.C.
March 15, 1982

Mr. Chairman and members of the subcommittee:

I am G. Marshall Abbey, Vice President of Travenol Laboratories, Inc. Appearing with me is Dr. James Winchester, a nephrologist and Assistant Professor of Medicine at the Georgetown University Medical School, who, at the conclusion of my statement, will be glad to answer any medical questions on dialysis, particularly CAPD, which you might have.

Travenol is a leading manufacturer of disposable dialysis supplies, both for hemodialysis and the new treatment modality, Continuous Ambulatory Peritoneal Dialysis (CAPD). Because of its role in the dialysis industry, Travenol is interested in all changes in that industry and therefore welcomes this opportunity to appear before you today.

With the limitations which I will express, Travenol endorses the proposed regulation issued by the Health Care Financing Administration and compliments HCFA on its studied approach and careful attention to Congressional intent: "to promote the efficient delivery of dialysis services and to provide for the increased use of home dialysis." Travenol will file comments on the proposal evidencing that endorsement, suggesting only minor changes and taking issue with one factual finding -- that relating to the cost of CAPD.

On the basis of admittedly limited data, the HHS audit agency found that the mean cost of CAPD was $342 per week. Travenol has reviewed the agency's data and also compiled some of its own and feels that the cost is even lower, approximately $317 per week.

Most of the criticism which has surfaced so far relates to whether the $132 and $128 base rates and the $4 differential between them are appropriate. Travenol takes no position on these issues, except to urge that the rates be set so as to keep hospital centers in operation, since, as I will demonstrate, the hospitals have been more active in encouraging the use of lower cost home dialysis.

My major purpose is to make sure that you appreciate the importance and the significance of the composite nature of the reimbursement rate. "Composite" means that the reimbursement will be the same regardless of the treatment modality and regardless of whether the patient is treated in a center or treated at home and monitored by the center. Since home dialysis, hemodialysis or CAPD, is lower cost than in-center dialysis, the composite nature of that rate will incentivize home dialysis and lower program costs.

One of the reasons for the current high program costs is that home dialysis has not been sufficiently utilized. At the end of 1981, only 18% of the Nation's kidney patients were dialyzed at home. Of those home patients, 54% were dialyzed by peritoneal dialysis and 46% by hemodialysis. The fact that we could do better, following correct standards of medical appropriateness, is shown by the fact that, in Canada, 26% of all patients are on CAPD alone. Here in our country, the percentage of home patients varies from state to state. For example, 32% of the kidney patients were treated at home in Minnesota in 1980 and in Indiana and Montana, the figures were 43% and 38%. Other such data, by state and foreign country, are attached.

Of particular interest to the subcommittee, I think, should be the identification of the types of centers which send patients home. On the basis of a Travenol survey, the statistics are as follows: hospital centers treat or monitor 54% of all kidney patients yet monitor 70% of all home patients. Free-standing centers, which treat or monitor 46% of all kidney patients, monitor only 30% of all home patients. To put it another way -- hospitals send 24% of their patients home; free-standing centers send 12%. These are today's facts, which indicate the important role played by hospitals.

The goal of the government, the patients and the dialysis industry should be to reduce costs. A composite rate which will result in increased use of home dialysis will help us to attain that goal.

Thank you.

Table 2. Dialysis Rates in the United States by State.*

State	Estimated Population in 1979 (Millions)	Number of Patients on Dialysis per Million Population	Percentage of Patients Having Home Dialysis	Transplant Rate per Million Population	Percentage of Dialysis Patients in "For-Profit" Units
Alabama	3.75	212	17	24	38
Alaska	0.38	52	20	0	0
Arizona	2.42	204	9	23	11
Arkansas	2.17	147	20	8	55
California	22.43	232	6	20	57
Colorado	2.73	190	23	19	52
Connecticut	3.10	207	5	15	15
Delaware	0.58	243	13	0	100
District of Columbia	0.65	983	3	122	53
Florida	8.77	274	6	11	48
Georgia	5.06	262	9	15	54
Hawaii	0.86	383	21	55	0
Idaho	0.90	67	23	0	0
Illinois	11.20	197	5	13	49
Indiana	3.40	172	43	16	0
Iowa	2.90	121	30	23	0
Kansas	2.35	130	26	8	4
Kentucky	3.49	119	9	21	60
Louisiana	3.99	238	6	15	58
Maine	1.09	121	8	15	53
Maryland	4.11	183	11	23	62
Massachusetts	5.76	223	10	27	47
Michigan	9.20	175	13	20	16
Minnesota	4.06	134	32	59	0
Mississippi	2.41	203	18	3	13
Missouri	4.85	170	21	26	10
Montana	0.78	109	38	0	0
Nebraska	1.56	113	6	23	0
Nevada	0.69	240	5	0	46
New Hampshire	0.88	85	8	0	73
New Jersey	7.31	242	14	11	24
New Mexico	1.23	173	13	24	62
New York	17.62	282	9	21	12
North Carolina	5.51	188	26	20	76
North Dakota	0.65	96	0	0	0
Ohio	10.72	155	11	24	14
Oklahoma	2.86	[illegible]	17	26	32
Oregon	2.52	[illegible]	26	27	35
Pennsylvania	11.72	210	14	18	21
Puerto Rico	3.32	159	9	3	64
Rhode Island	0.92	319	1	0	70
South Carolina	2.87	216	13	10	55
South Dakota	0.68	81	0	0	0
Tennessee	4.36	207	20	28	10
Texas	13.24	210	11	19	66
Utah	1.36	174	46	10	28
Vermont	0.49	122	28	22	0
Virginia	5.05	265	14	23	55
Washington	3.88	171	59	18	0
West Virginia	1.88	148	31	3	9
Wisconsin	4.72	120	20	37	9
Wyoming	0.45	20	0	0	100
Total	221.82	204.7 †	13.1 †	19.4 †	36.1 †

*All data were adapted from figures supplied by the End Stage Renal Disease section of the Health Care Financing Administration, Department of Health and Human Services, and from the Population Estimates and Projections, Series P-25, No. 876, February 1980, United States Department of Commerce, Bureau of the Census.

†Mean figures calculated from total numbers.

Table 1. Dialysis Rates in Europe and Israel.*

Country	Number of Patients on Dialysis per Million Population	Percentage of Patients Treated at Home
Western Europe and Israel		
Austria	69	7
Belgium	123	8
Denmark	80	30
France	133	20
Ireland	47	34
Israel	144	15
Italy	120	12
Netherlands	92	9
Norway	31	7
Portugal	6	0
Spain	78	7
Sweden	65	22
Switzerland	127	24
United Kingdom	53	65
West Germany	117	25
Eastern Europe		
Bulgaria	17	0
Czechoslovakia	23	0
East Germany	31	0
Hungary	12	0
Poland	8	1
Yugoslavia	43	1

*Source: Combined Report on Regular Dialysis and Transplantation in Europe, IX, 1978. Pitman Medical, Tunbridge Wells, and the Council of the European Dialysis and Transplant Association.

SUPPLEMENTARY STATEMENT
ON
RENAL DIALYSIS REIMBURSEMENT ISSUES
BEFORE THE
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON FINANCE
UNITED STATES SENATE
THE HONORABLE DAVID DURENBERGER, CHAIRMAN

Travenol Laboratories, Inc.
1 Baxter Parkway
Deerfield, Illinois 60015

April 5, 1982

Travenol is a leading manufacturer of disposable dialysis supplies, both for hemodialysis and for the new treatment modality Continuous Ambulatory Peritoneal Dialysis (CAPD). Because of its role in the industry, Travenol is interested in all changes in that industry and therefore welcomes this opportunity to provide additional information on renal dialysis reimbursement issues.

The proposed regulation issued by the Health Care Finance Administration (HCFA) provides for the increased use of home dialysis and accomplishes this through the use of a dual composite rate for reimbursement. Composite rate means that reimbursement will be the same regardless of treatment modality or site of treatment, center or home. Travenol endorses this intent as an effective means of reducing the cost of the end stage renal disease program.

CAPD has been a significant factor in the growth of home dialysis in the last three years. Today there are just over 11,900 home dialysis patients (19% of all chronic dialysis patients) compared with approximately 5,000 home patients at year end, 1978. The 5,000 current CAPD patients account for the majority of the net growth in home dialysis during this period.

In the course of the Subcommittee on Health hearings on the subject of proposed renal dialysis reimbursement regulations, the viability of CAPD as a lower cost and medically efficacious dialysis alternative was questioned. Hospitalization rates along with death and abandonment statistics were cited to question the suitability of this new treatment modality.

Travenol wishes to present more extensive data both on hospitalization rates and on death and abandonment to demonstrate that CAPD, even at this early state in the development of this new treatment modality, does not offer greater risk either of hospitalization or of death than does hemodialysis.

CAPD is a well accepted and effective dialysis treatment for end stage renal disease. The advantages of the continuous dialysis offered by CAPD over intermittent forms of dialysis (such as hemodialysis) in controlling blood chemistries and fluid balance are extensively reported in the literature. The fact that at year end 1981, only two years after CAPD was first covered under reimbursement for end stage renal disease, over 8% of the 60,000 U.S. dialysis patients are being treated by CAPD and that over 500 of the 1,050 U.S. chronic dialysis facilities offer CAPD indicates the wide acceptance of this treatment. This is particularly true given the economic disincentives which exist under current reimbursement regulations.

Death and Abandonment

To reach a meaningful comparison of CAPD to hemodialysis, patient death rates and treatment abandonment rates must be separated. Death rates are best measured by actuarial patient survival methods. Similar actuarial life table analyses are the most appropriate measures of technique survival (abandonment), however, this data does not exist for hemodialysis. Combined death and abandonment statistics for CAPD cannot be judged against hemodialysis patient survival data alone.

Reported CAPD patient survivals run higher than reported for in-center hemodialysis or total dialysis populations (Table I). Cumulative one and two year survival rates on CAPD are 80% to 90% and 65% respectively. This compares to 70.8% and 53.2% for in-center hemodialysis and 78% and 66% for all forms of dialysis combined. While these figures are not directly comparable because they do not represent matched patient populations, they are drawn from large patient populations and suggest that the death rate in the CAPD population is less than in the hemodialysis population or in the dialysis population as a whole.

Reported abandonment or procedure discontinuation rates for CAPD (which include transplant among other reasons) shows substantial variation (Tabel II). One and two year technique survival rates range from approximately 60% and 32% respectively in the European Dialysis and Transplant Registry and in current U.S. CAPD Registry data to 80% and 58% respectively over a three year monitoring period in all Toronto hospitals. Currently 30% of all 1,142 dialysis patients in Ontario are treated by CAPD.

Comparable data does not exist for hemodialysis. However, a study published in Kidney International (Vol. 21, 1981, p.p. 78-83) reported that over a 5 year period in the State of Michigan, 836 of 2,396 in-center hemodialysis patients, or 35% of the total, left hemodialysis for reasons other than death. This data coupled with a hemodialysis death rate higher than CAPD implies a significant death and abandonment rate associated with in-center hemodialysis.

Certain additional considerations affect the discontinuation rate from CAPD. CAPD is considered a safe treatment in that complications are not imminently life threatening and CAPD requires only a short training period. As a result, often a trial period is used for patient selection as opposed to rigorous pre-screening of candidates as is used for transplant or home hemodialysis patient selection. Secondly, because of the advantages CAPD offers for problem patients such as those with cardio-vascular problems, CAPD receives a number of high risk patients who could not tolerate hemodialysis. In the U.S. CAPD registry which followed 482 patients for the first nine months of 1981, 34.5% of the patients leaving CAPD for reasons other than death, transplant, or return of renal function left because of medical complications not related to CAPD. Finally, CAPD is a self care, home dialysis treatment which has, as a consequence, a more complicated set of psycological and socialogical factors associated with treatment success. Failure to adapt to self care dialysis has the acceptable alternative of a return to in-center, total care dialysis. There is no readily acceptable alternative to which to retreat from in-center dialysis.

Hospitalization

Hospitalization measured in days per patient year are not significantly greater for CAPD than for hemodialysis (Table III). The Province of Ontario, Canada, Registry (where 30 % of the 1,142 dialysis patients are on CAPD) report an average of 20.3 hospital days per patient per year for CAPD. Preliminary data from the NIH sponsored U.S. CAPD Registry indicate 25.7 hospital days per patient per year on CAPD.

These hospitalization rates compare to an average of 18.7 hospitals per patient per year for hemodialysis based on the total U.S. patient population over 1977 to 1980 as reported by the Health Care Finance Administration. This data is only indicative of the relative hospitalization rates between CAPD and hemodialysis and cannot be considered conclusive since it does not represent matched patient populations.

Any difference that might exist in hospitalization rates between CAPD and hemodialysis is even less significant given that 17% to 20% of CAPD hospital days are for catheter implantation and initial patient training (Table IV). These are one time hospitalizations for each new CAPD patient. This component of aggregate CAPD patient hospitalizations will decrease as new CAPD patients become a smaller fraction of a total CAPD patient population.

Evolving trends in CAPD patient care will continue to reduce average hospital rates. Currently over 50% of all incidences of peritonitis are treated on an out patient basis, a significant change from initial CAPD protocols where virtually all peritonitis cases were hospitalized.

In summary, CAPD is a widely accepted and practiced new alternative in dialysis therapy and is demonstrating a continuing constant growth in spite of economic disincentives under current reimbursement regulations. Provisions in the proposed regulations to increase the use of home dialysis will remove these economic disincentives with the result being continued growth of CAPD and increased ESRD program cost savings due to the increased use of this lower cost, home therapy.

There is no evidence in the current body of data to indicate a significantly greater risk of either excessive hospitalization or death and abandonment with CAPD compared to hemodialysis. As a consequence, CAPD does not carry either an increased medical risk or a hidden cost penalty from these considerations.

It is important to note that the current body of data is only indicative and not conclusive in comparing CAPD to hemodialysis. Outcome data from matched patient populations does not exist. Variations from dialysis center to dialysis center show wide variation, data from any one facility must be considered anecdotal, not definitive. It must also be realized that CAPD is still a new and developing treatment and improvements in outcome measures can be expected as techniques, devices, and patient selection advance. The real advantages of CAPD over hemodialysis may not be realized for several more years. As an example, it has been recently reported (New England Journal of Medicine, March 18, 1982) that survival of diabetics on CAPD is significantly greater than on hemodialysis with a two year CAPD survival of 81% compared to European Dialysis and Transplant Registry two year survival for diabetics of 40%.

We trust this additional information serves to clarify what have become controversial issues relating to the medical and cost saving potential of CAPD. Attached as an appendix is a letter to the Honorable Richard S. Schweiker, Secretary of Health and Human Services, which further speaks to these medical issues and to the body of data supporting these conclusions.

TABLE I

PATIENT SURVIVAL - LIFE TABLE ANALYSIS

Treatment	Source	Number of Patients Starting	1 Year Cumulative Survival	2 Year Cumulative Survival
All Forms of Dialysis	Missouri Kidney Program Annual Report 7/1/80 - 6/30/81	2596	78.9%	66.3%
"	Michigan Kidney Registry Analysis of Survival of End Stage Renal Disease Patients, Weller, et al.; Kidney International, Vol. 21, (1982; pp 78-83)	2396	78.1%	61.2%
In-Center Hemodialysis	Michigan Kidney Registry Analysis of Survival of End Stage Renal Disease Patients, Weller, et al.; Kidney International, Vol. 21, (1982; pp 78-83)	1560	70.8%	53.2%
CAPD	European Dialysis and Transplant Registry - 1980	1728	80%	65%
"	Pilot Study - NIH Sponsored CAPD Registry - 1981	381	89.5%	--
"	Toronto Experience (4 Hospitals) 9/77 - 10/81	409	94% (Non-Diabetic) 92% (Diabetic)	80% (Non-Diabetic) 70% (Diabetic)

TABLE II

PATIENTS REMAINING ON CAPD (LIFE TABLE ANALYSIS)

Source	Patients Starting	1 Year Cumulative Success	2 Year Cumulative Success
European Dialysis and Transplant Registry	1728	57%	32%
U.S.A. CAPD Registry - 1981 Pilot Study	381	60%	--
University of Missouri Experience	32	72%	63%
New England Journal of Medicine 306:625, 1982 Toronto Western Hospital	20 (Diabetics)	87%	76%
Peritoneal Dialysis Bulletin 1:24,81 Toronto Western Hospital	132	80%	62%
Toronto Experience (4 Hospitals) 9/77 - 10/81	409	80% (Non-Diabetic) 79% (Diabetic)	58% (Non-Diabetic) 56% (Diabetic)

TABLE III

SUMMARY - COMPARATIVE HOSPITALIZATION DAYS

	Hospital Days Per Patient Year	Source of Data
Hemodialysis:	18.7	Health Care Finance Administration - All U.S. Patients 1977 - 1980
CAPD:	20.3	Province of Ontario Registry Data (St. Catherine Hospital)
	26.3	Toronto General Hospital (166 Patients; 76,536 CAPD Treatment Days)
	25.7	NIH Sponsored CAPD Registry (562 Patients, 298.7 Patient Years)
	23.3	Georgetown University (70 Patients; 24,910 CAPD Treatment Days)
	14.5	Toronto Western Hospital (132 Patients, 60.2 Patient Years - 1980 Data)

TABLE IV

DISTRIBUTION OF HOSPITAL DAYS BY CAUSE OF HOSPITALIZATION - CAPD PATIENTS:

	TORONTO GENERAL HOSPITAL	GEORGETOWN UNIVERSITY
Initial Hospitalization New Patient	5.0%	9.9%
Renal Failure and General Medical Complications	30.1%	23.6%
Transplant	10.0%	8.8%
Catheter Implantation and Training	17.7%	25.3%
CAPD Related:		
Peritonitis	25.8%	12.3%
Catheter Complications	6.4%	9.0%
Out Patient Admissions	--	8.9%
Other	5.0%	2.2%
	100.0%	100.0%

Hospitalization Rates:

Toronto General Hospital (166 patients; 76,536 treatment days) - 26.3 days per patient year.

Georgetown University (70 patients; 24,910 treatment days) - 23.3 days per patient year.

THE AUSTIN DIAGNOSTIC CLINIC
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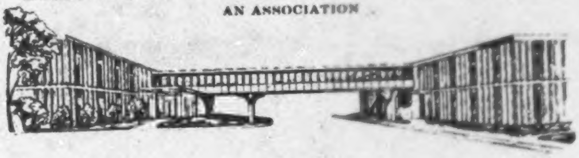

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INTERNAL MEDICINE

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Michael Rotman, M.D.
Robert W. Pederson, M.D.

DERMATOLOGY
Thomas W. Schulze, M.D.

ENDOCRINOLOGY
Henry Renfert, M.D.
Terry M. Collier, M.D.
Ross P. Chiles, M.D.

GASTROENTEROLOGY
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Charles E. Felger, M.D.
George E. Kitzmiller, M.D.
Rambie L. Briggs, M.D.
Thomas R. Liebermann, M.D.

HEMATOLOGY/ONCOLOGY
Leonard J. Sayers, M.D.
Dennis E. Welch, M.D.
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INTERNAL MEDICINE
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John R. Marietta, M.D.

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Jonathan F. Decherd, M.D.
James D. Lindley, M.D.
Gerald A. Beathard, M.D.
W. Scott Moore, M.D.

NUCLEAR MEDICINE
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PULMONARY DISEASES
George J. Handley, M.D.
Robert K. Emerson, M.D.
Harold D. Cain, M.D.

RHEUMATOLOGY
Homer R. Goehrs, M.D.
Marshall R. Sack, M.D.
James E. Crout, M.D.

NEUROLOGY
ELECTROENCEPHALOGRAPHY
ELECTROMYOGRAPHY
Everett G. Heinze, Jr., M.D.
Harold Skaggs, Jr., M.D.
Jerry R. Tindel, M.D.
Thomas A. Hill, M.D.

RADIOLOGY AND
NUCLEAR MEDICINE
Bethea W. Brindley, M.D.
Timothy J. O'Neill, M.D.
Charles L. Mott, M. D.

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ASSIST. ADMINISTRATOR
Henry E. Ross

April 2, 1982

The Honorable Richard S. Schweiker
Secretary of Health and Human Services
200 Independence Avenue, S. W.
Washington, D. C. 20201

Dear Sir:

We have been involved in the development and evaluation of Continuous Ambulatory Peritoneal Dialysis (CAPD) since its inception. We have also collaborated in the numerous studies of CAPD sponsored by the National Institutes of Health. At the moment, we are conducting the National Institutes of Health Registry of CAPD.

As you are aware, new proposed regulations for end stage renal disease (ESRD) reimbursement encourages home dialysis in contrast to the previous reimbursement policy. Because of the many concerns over reimbursement per se, some parties are challenging the proposed advantages of CAPD as an alternative form of home dialysis therapy and have proposed that the potential cost saving benefits of CAPD are outweighed by a high drop out rate and a large number of hospital days per patient year. Some individuals have expressed doubt relating to medical indications for, and efficacy of, CAPD in the treatment of patients with ESRD. We would like to address some of these issues.

Hemodialysis Has Many Problems.

Hemodialysis is certainly not a trouble free form of therapy. Although it is difficult to determine drop out rates for chronic hemodialysis in this country, recent studies have reported mortality rates on chronic hemodialysis. In a report from the state of Michigan published in Kidney International (Vol. 21, p. 78, 1982) actuarial survival on center hemodialysis for 1,560 patients was 54% at two years. The 1981 Annual Report of the Missouri Kidney Program for the state of Missouri shows that two year cumulative survival on hemodialysis for 1,735 patients was 57.5%. Many of these deaths relate to cardiovascular problems often aggravated by the process of hemodialysis. Other problems with hemodialysis include repeated problems in maintaining a blood access, control of blood pressure, and recurring symptoms related to the rapid changes in body chemistries and fluid volumes which occur with the intermittent application of this therapy. Another unfortunate characteristic of chronic hemodialysis is the risk of sudden death. This may occur as a result of rapid decreases in blood pressure with resulting strokes and myocardial infarctions, sudden arrythmias, air embolis or massive hemorrhage into the dialyzer.

The problems with hemodialysis are exemplified by the rapid growth of Continuous Ambulatory Peritoneal Dialysis. In just a few years, over 500 centers in the United States have initiated CAPD programs to over 5,000 patients. If hemodialysis were problem free, why would there be such interest in an alternative form of therapy? This is of particular significance since CAPD has had major fiscal disincentives related to its growth.

Drop Out Rates and CAPD.

Under separate letter, Dr. Nolph has pointed out his concern that very preliminary data from the National Institutes of Health CAPD Registry have been used to demonstrate high drop out rates from CAPD. This data was compiled with very small patient numbers in pilot phases of the Registry. There is no comparable data from hemodialysis populations that are appropriately matched for comparison to this data. It is important also to note that the CAPD Registry includes many newly formed CAPD programs which are initiating this therapy in problem patients. Many centers initiate CAPD on a trial basis to determine if patients are capable of performing CAPD. A trial of CAPD is often utilized as a patient selection technique. Other forms of dialysis are difficult to apply to some patient groups. CAPD is considered to be quite safe, requiring only a short training period. Therefore, a trial of CAPD is considered reasonable. Patient survival on CAPD has been quite good even in the face of new programs beginning this therapy in their problem patients. As an example, two year cumulative survival of 32 patients at the University of Missouri was 85%. For 132 patients at the Toronto Western Hospital it was 82%, and 81% in 20 patients with diabetes mellitus at this same hospital. A preliminary analysis of the CAPD Registry data in the U.S.A. in 381 patients showed a one year cumulative survival of 89.5%. References: Peritoneal Dialysis Bulletin, Vol. 1, p. 24, 1981, New England Journal of Medicine, Vol. 306, p. 625, 1982, and CAPD Registry data submitted to the National Institutes of Health, April 1, 1982.)

We have reviewed two year cumulative survivals in chronic hemodialysis patients from the European Dialysis and Transplant Registry. The survival rates were 64.7% for the age group 55 to 64. We have mentioned the results in the state of Michigan showing a 54% two year cumulative survival. The results of the Missouri Kidney Program Annual Report show a 57.5% survival.

Thus, the evidence suggests that CAPD is a safe technique. Most reported deaths have been unrelated to the CAPD technique. CAPD is not associated with many of the life/death risks of hemodialysis mentioned above. Rapid fluctuations of blood pressure are unusual, blood access is not required, rapid changes in body chemistries and sudden arrythmias are not characteristic of CAPD. Neither air embolis nor massive blood loss are a problem.

In summary, CAPD would appear to be a safe technique with a short training period. Many centers prefer to initiate a trial of CAPD in the problem patients. High turn over rates should not be used to condemn CAPD as it does allow patients to try a safe and simple home dialysis technique. Many succeed, as exemplified by the continued growth of the number of patients on CAPD.

It would appear that the medical community does not view the CAPD drop out rates as a detriment to the continued growth of CAPD. Patients continue to elect CAPD and many centers are initiating CAPD programs. The widespread enthusiasm of the medical community is illustrated by the very large number of centers (more than 500) now offering CAPD therapy.

Hospital Days.

Many studies, including the preliminary data from the CAPD Registry and studies from Canada, suggest that patients on CAPD average 20 to 25 days in the hospital per patient year. Dialysis related complications accounted for only 50.4% of these days in the CAPD Registry study. Cardiovascular problems and other medical problems accounted for 42.9%. Training days accounted for 6.7%. It is likely that the cardiovascular and other medical problems of the patients would have occurred regardless of the dialysis technique used. These patients may have required more hospitalization if these underlying cardiovascular health problems had been aggravated by hemodialysis -- a situation which often exists. We suspect that population matched studies would not reveal major differences between CAPD and hemodialysis patients in terms of days in hospital.

Another perspective relates to the question of hospital days. Center hemodialysis patients without complications make contact with nurses and physicians three times per week for a total of 156 times per year. This physician/nurse contact, which is a requisite of center hemodialysis results in many of the extra costs of center hemodialysis which appear as overhead expenses. CAPD patients without complications require medical personnel contact only every

4 to 6 weeks. Thus, 12 visits per year coupled with 25 hospital days would result in 37 contacts with the medical community per year. A better comparison of the cost impact of the two techniques is not in the difference in hospital days (and we even doubt this difference if matched studies were done) but in how many days the patients are leading their own lives free of contact with the expensive medical community. Obviously, such free days enjoyed by the CAPD patient population result in cost savings.

Peritonitis and CAPD.

One of the major reasons for patients discontinuing CAPD relates to the inability to carry out the technique without contaminating the system. The skills of performing CAPD require motor coordination. Some patients simply do not have that capability. However, peritonitis is usually very responsive to early treatment and results in brief morbidity and an extremely low mortality. The great majority of peritonitis cases are currently treated on an outpatient basis. We anticipate that developments now on the horizon will reduce the risks of peritonitis well below those now observed (1 to 2 episodes per patient year) and this, in turn, will impact markedly on hospitalization days and drop out rates.

The Medical Benefits of CAPD.

Thus far, we have addressed those issues which have been raised to suggest that CAPD will not provide an alternative therapy for large numbers of patients over long periods. We have challenged those allegations. CAPD has striking advantages and we anticipate major long term impact from the delivery of this form of therapy. This impact will demonstrate itself both economically to the government and to the benefit of the patients.

As mentioned, CAPD is a very low risk procedure and is not associated with any sudden death risks of which we are aware. It provides continuous, steady dialysis, very similar to the continuous physiologic effects of normal kidneys. Rapid fluctuations in blood pressure and body chemistries are absent and this contributes enormously to the feeling of well-being that these patients experience. Patients usually exhibit increased appetite, strength, red blood cell count and ease of blood pressure control. In the diabetic patients, a far better control of blood glucose can be achieved than has previously been possible with any other form of dialysis. Recent studies published in the New England Journal of Medicine suggest that CAPD may give the best results in patients with diabetes mellitus with low mortality rates, low drop out rates and improved rehabilitation. The results in patients with diabetes mellitus so far have been far better than previously reported. CAPD has also allowed dialysis in infants and small children in an acceptable fashion. This was not previously possible. CAPD is, in the opinion of most pediatric nephrologists, the treatment of choice in the pediatric patient awaiting transplantation. If one only considers the pediatric and the diabetic groups, CAPD may be the treatment of choice for up to 30% of the ESRD population.

We would reiterate that adequate comparisons between available techniques of drop out rates and survival can not be fairly made in the absence of well matched, controlled trials. Nevertheless, survival rates from multiple reports of CAPD are as good or better than those available on hemodialysis, despite the much mentioned fact that problem patients are frequently placed on CAPD.

Summary.

It is our hope that issues of reimbursement will not promote brief negative descriptions of those forms of therapy which may not be fiscally advantageous to certain members of the medical community. CAPD, like hemodialysis, is not perfect. There are problems and complications. CAPD does, however, offer many advantages and is clearly a well established, proven form of therapy -- and the best form of therapy for a substantial percentage of patients. It is not our contention that it is the best therapy for all patients. It is not our purpose to downgrade hemodialysis or to imply that it is not the most logical choice of therapy for many patients. Until a perfect form of renal replacement therapy is available, we must apply all of the available forms of therapy to meet the special needs of each patient. Hopefully, this will allow the patient to have the freedom to choose that technique which is best suited to his needs and capabilities without undue fiscal restraints.

We would discourage comparisons of CAPD and hemodialysis at the present state of knowledge which attempt to describe one form of therapy as better than the other. Appropriate matched comparisons are not available and most differences probably reflect the influence of other factors such as patient selection rather than differences between techniques. CAPD is undergoing constant improvements and will have dramatically different characteristics in the near future. Data now evolving from the CAPD Registry are still very preliminary with only small numbers available for actuarial analysis. There is no appropriate comparable hemodialysis data.

We hope these comments have been helpful to you as we know you are hearing from many different sources. We hope we speak for those 500 centers which are enthusiastically offering CAPD to their patients. We would be happy to provide additional information as you may require to reach decisions on these critical issues. Please feel free to contact us at any time.

Sincerely,

Jack W. Moncrief MD

Jack W. Moncrief, M.D.
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G. MARSHALL ABBEY
Vice President, Secretary
and General Counsel

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April 5, 1982

The Honorable David Durenberger
Chairman, Subcommittee on Health
Committee on Finance
United States Senate
Suite 2227, Dirksen Senate Office Building
Washington, D.C. 20510

Attention: Ed Danielson
Ed Mihalski

In response to your request I am submitting additional information regarding the Canadian experience with home dialysis. You should be aware that little data exists at this time but what data is available is incorporated in our statement, which is attached.

I am also enclosing some additional information on C.A.P.D. that will serve to correct the record established during the March 15th hearing by one or more of the witnesses.

Twenty-six percent of all patients in Canada are on CAPD according to your statement. Are there any statistics that show what that treatment causes in terms of increased hospitalization, morbidity or mortality in Canada or in this country? Some claims have been made that CAPD is not cost effective because of increased hospitalization costs.

Sincerely yours,

G. Marshall Abbey

UNIVERSITY OF MISSOURI-COLUMBIA

School of Medicine

Department of Medicine
Division of Nephrology

M472 Medical Center
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April 2, 1982

The Honorable Richard Schweiker
Secretary of Health and
Human Services
400 Independence Avenue SW
Humphrey Building
Washington, DC 20510

Dear Mr. Secretary:

It has been brought to my attention that life table analyses from the 1981 pilot study of the National Registry for CAPD are being used by some to compare hemodialysis and CAPD success rates. Since the National Registry for CAPD was established as a project funded by the National Institutes of Health under the Chronic Renal Dialysis Program of NIADDKD, and I have been appointed as the principal investigator, I feel compelled to inform you that this represents gross misuse of the data.

These analyses were distributed to participating centers in the pilot phase of data collection which took place during 1981. This pilot study was done as preparation for monitoring the entire national data commencing the last quarter of 1981. The data were distributed as an example of one of the many types of analyses we will be doing with national data. The life table analyses were carried out only on those patients who began CAPD during 1981 at those centers participating in the pilot study.

Let me enumerate the reasons why these analyses may not fairly characterize CAPD and why they should not be used for comparisons of CAPD and hemodialysis success rates:

(1) CAPD was defined as commencing with training. Since CAPD training is easy to initiate, many centers provide a short period of training and a short experience with CAPD as a trial to help the patient and the doctors decide what technique is best for them. Such a trial period is not so common with other techniques.

(2) We commenced this pilot actuarial analysis using data only from patients who started CAPD during the year 1981. Of the 213 patients who so qualified, very few had the opportunity to be followed beyond the first three months. The analyses for the third and fourth quarters are based on very small numbers (48 and 9). Actuarial projections based on small numbers and early experiences are usually not valid. As a matter of fact, subsequent data now being processed indicates substantially better results.

(3) The figure of 43% remaining on CAPD at the end of one year reflects projections from small numbers and reflects the effects of dropouts for all reasons. These include many positive reasons, such as recovery of renal function and transplantation. Patient survival projected from the same analyses was 86% for one year. This figure is as good, or better, than most hemodialysis experiences, but again is based on small numbers only.

(4) During this same period there were actually 482 patients on CAPD at the pilot centers. Most of these had started CAPD prior to 1981. As of late 1981, 78.4% of these 482 patients were still on CAPD. This gives a different impression than the actuarial analysis of those patients who started CAPD during the year. It mainly illustrates the need for more data collected over long periods of observation.

(5) Finally, even if the life table analyses from the CAPD Registry were based on long periods of observations and large numbers of patients, comparing the results with hemodialysis results would still not be appropriate. Unless prospective randomized trials are carried out, we are always dealing with two different populations. This population of CAPD patients might have fared worse on hemodialysis than on CAPD.

In summary, I would hate to see this data used to promote CAPD or hemodialysis over the other. This data is early Registry data beginning our attempt to characterize the population of patients on CAPD. It is only preliminary and is influenced by many features of the CAPD population. Hemodialysis results (that are better or worse) can be found, depending on the source. The differences probably reflect patient selection and population characteristics as much, if not more, than choice of technique per se.

Sincerely yours,

Karl D. Nolph, M.D.
Director, Division of Nephrology and
Professor of Medicine
Department of Medicine
University of Missouri-
  Health Sciences Center and
H.S. Truman V.A. Hospital
Columbia, MO 65212

KDN/ca

THE HONORABLE DAVE DURENBERGER R. (MINNESOTA)
CHAIRMAN OF THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON FINANCE
TESTIMONY TO BE PRESENTED MONDAY, MARCH 15TH
AT THE HEARING TO REVIEW THE PROPOSED PROSPECTIVE REIMBURSEMENT
RATES FOR THE END-STAGE RENAL DISEASE PROGRAM

PRESENTOR: BARRY VON HARTITZSCH, M.D., F.A.C.P., F.R.A.C.P.
CONSULTANT NEPHROLOGIST
4436 SOUTH HARVARD, TULSA, OKLAHOMA 74105

Senator Durenberger -

The thrust of the proposed rules published in the Federal Register Department of Health and Human Services, 42 CFR Part 405 (2-12-82), is obviously to promote cost saving through home dialysis. A composite reimbursement rate has been advocated to encourage cost savings through incentives for home dialysis.

If such a measure is to be mandated, two important questions need to be answered:

> Is the treatment going to be better?
> Is the treatment going to be more cost effective?

No one questions that home hemodialysis without a paid home-aide, as has always been practised, provides a longer survival at approximately a 25% savings. However, so much of the thrust of this new legislation is based on the unsupported expectations of a new home therapy - Continuous Ambulatory Peritoneal Dialysis (CAPD). It is very dangerous to assume that because it is a home therapy, it will be cost effective. If CAPD is the means by which 25-50% of center dialysis patients are to be moved to home dialysis, then we can say, right up front, that without adding another patient to the dialysis pool, the enactment of these regulations should increase, not decrease, the cost of the Renal Program by 12½ to 25%. Each patient placed on CAPD, whether he is an ideal candidate or not, will cost at least 30% more during the first year (and, probably, each subsequent year) than if he were treated in an independent hemodialysis center. Furthermore, the treatment is decidedly inferior to center dialysis for most patients, with 50-70% dying, or returning to center dialysis within one to two years.

This data was not collected for this particular hearing. I have just been through Health Planning hearings, trying to get approval for a new dialysis unit. The number of patients presenting with end-stage renal failure in my locality, and the growth of dialysis positions during the past three to four years, just did not tally, until it was realized that there were a large number of deaths in the death column. This led to an analysis of the survival rates for different modes of home and hospital therapy, and, from there, to an analysis of the complication rate and cost benefit data, as analyzed from the number of days in the hospital. When I saw these new regulations, I felt it my duty to present to you this rather sobering data.

This is data from the Hillcrest Medical Center in Tulsa, Oklahoma, an institution with a lot of experience in peritoneal dialysis therapy. I have presented data comparing intermittent peritoneal dialysis and hemodialysis at national and international meetings from 1976 to 1978, which set the stage somewhat for wide acceptance of CAPD. Based on experience in peritoneal dialysis, Hillcrest would be expected to run a better than average CAPD program.

The accompanying figure compares the survival rates of different modes of therapy - how many patients we can expect to remain on these therapies at each interval of time. I have used the latest center hemodialysis rates from the European Dialysis and Transplant Registry, where countries, in the main, have a selection policy similar to the U.S.A. U.S.A. national figures have always been similar, but our figures for the past four years have been bound up, still, in Health and Human Services computers. Recent quoted figures for a national medical care unit in Boston, fit nicely on these curves for older patients matched for age with our CAPD patients. It would have been a major undertaking for me to construct a curve for Hillcrest hemodialysis survivals, since this would have required many hours of work in Medical Records, screening a large number of charts. The figures for intermittent peritoneal dialysis in older patients, hospital based, from June, 1976, and home intermittent peritoneal dialysis from 1978, did not live up to our initial high expectations for these therapies - with no patients surviving beyond 24 months. The graph shows CAPD to be a little better, with Hillcrest Medical Center showing a combined death and drop-out rate for CAPD, not much better than the European figures of 50-70% drop-out rate at one and two years. I am not saying that CAPD is not an excellent treatment for some people. I have some excellent patients, but, unquestionably, on a large scale, longevity and survival on CAPD are much inferior to standard center hemodialysis.

In comparing the cost of two programs, one should include the cost of treating complications inherent in a particular technique. In other words, not just the cost of the dialysis supplies delivered to the home, but the cost of hospitalizations that that patient experiences as a result of his therapy.

When I review the charts of nineteen patients, who have completed at least one year on CAPD at Hillcrest Medical Center, I found that these patients spent an average 35, ± 27 days in hospital during the first twelve months of therapy. A group of similarly aged, disease-matched controls, commenced on hemodialysis spent an average of 15, ± 8 days in hospital - a difference highly significant at the P greater than 0.0025 level. Many people will say that the worst patients receive CAPD, the best having been allocated to hemodialysis. In Tulsa, distance from the dialysis unit has been our criteria for allocation to center dialysis or home intermittent peritoneal dialysis, and, more recently, CAPD. Most of the hemodialysis controls came from one physician (myself), who, for the past 18 months elected to treat his older patients on hemodialysis, while the other three physicians continued theirs on CAPD. To complete the age matching and to match equally the number of diabetic patients, I was forced to go back a few years and take age-matching diabetic patients who had been allocated to intermittent peritoneal dialysis (today, these patients would have gone to CAPD), and count the first twelve months of hemodialysis therapy after they were changed from peritoneal dialysis because of failure of the peritoneal cavity. A genuine effort has been made to eliminate any bias that worse patients were treated by CAPD.

Several of my colleagues expressed concern that the ischemic limbs that occured in two CAPD patients, were real but very unusual complications of CAPD, and one patient who was placed on CAPD after six years on hemodialysis, who spent 104 days in hospital, could skew the results. Thus, when these three were removed, 16 CAPD patients had a mean of 25 ± 11 hospital days. When the three most hospitalized hemodialysis patients were removed, the remaining 16 had a mean of 13 ± 4 hospital days. This twelve day difference is highly significant at P greater than 0.001 level. A difference of twelve days at what cost?

The average daily cost for CAPD patients at Hillcrest Medical Center was just over $520. At another Tulsa hospital, offering CAPD backup, it was $720. At this hospital, a higher dialysis charge was made because it was believed that the sick patient under the influence of pain medications, cannot perform the CAPD exchanges without significant risk of contaminating his peritoneal cavity. The dialysis unit must accept responsibility for trying to keep the peritonitis rate down by completing every exchange while the patient is hospitalized.

I felt that a daily hospital rate of $520 to $720 would probably cover the costs for most hospitals providing back-up CAPD therapy across the country. However, my figures may be very conservative, for I was informed yesterday that an $800/day average had been mentioned at a recent meeting. However, taking the conservative approach, twelve additional hospital days for each CAPD patient, means $6,240 to $8,640 additional costs that must be included in the total CAPD costs. Using the mean data the Health Care Financing Administration (HCFA) has used in determining the proposed rates, let us compare the first year cost of independent center hemodialysis with hospital center dialysis and CAPD. See Table I. When hospital costs are included, hemodialysis costs in an independent center are $4,000 less expensive than hospital center hemodialysis and $8,000 less expensive than CAPD. To put it another way, CAPD is 30% more expensive than independent center hemodialysis.

HCFA officials have probably not stopped to consider why there is a differential of $28 between the mean hospital center and the mean independent center. The independent center receives 80% reimbursement from Medicare. Private insurance carried by 1/4th to 1/2 of the patients (I am assuming the Oklahoma experience to be a national trend), to be conservative, 1/4th accounts for another 5%. An efficient unit must be able to cover all expenses by making a profit at 85% of the present $138 screen. Since hospital units get reimbursed their costs, there has been no incentive for hospitals to be cost-effective. In fact, the higher they keep their costs, the more money they can siphon off the Medicare trust funds at the end of the year, when their bad debts are paid.

Under the proposed plan of $128 for independent dialysis units, and $132 for hospital-based units, hospital dialysis costs will fall by $6, while independents can increase by $20, since they now will be reimbursed bad debts. How much more money will this cost the End-Stage Renal Program?

As a physician who works in a hospital dialysis center and who is planning a freestanding unit, I have no doubts that a freestanding unit can provide a better and more cost-effective dialysis treatment.

The whole thrust of these proposed regulations seems to be to kill the "for profit" concept of medicine, a move that is in total opposition to the pro-competition health bills the Reagan Administration is planning to present this year. The concept that cost efficient delivery of health care should not be accompanied by a reasonable reward for effort should not be so intolerable that efforts to eliminate it result in a 25 - 30% increase in the cost of the End-Stage Renal Program.

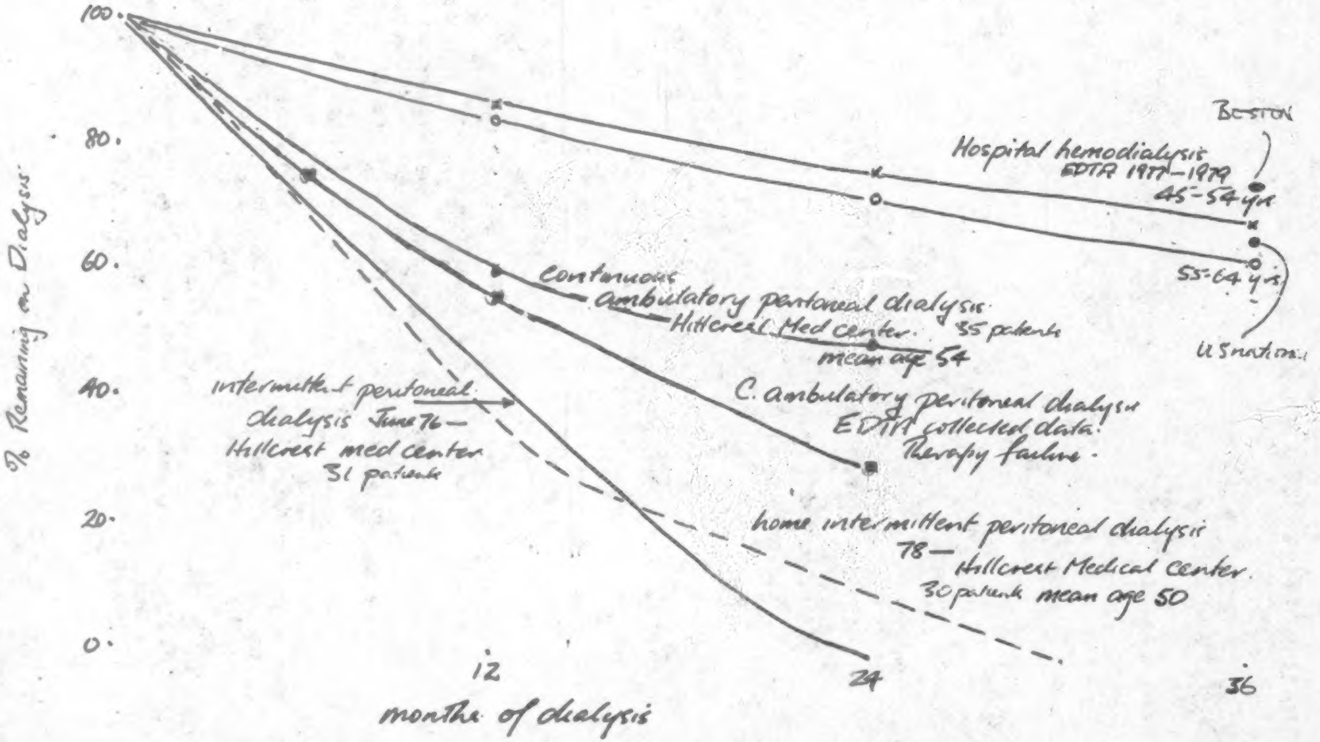
TABLE I

COMPARATIVE DIALYSIS COSTS

	INDEPENDENT CENTER	HOSPITAL CENTER	CAPD
Number of Dialyses x Cost of Dialysis	(156 - 6) x 107.66	(156 - 6) x 135.53	145 x 114
	$16,149	$20,329	$16,530
Hospitalization-Daily Rate	$520 - $720	$520 - $720	$520 - $720
Days in Hospital:	12: $6,760-$9,360	12: $6,760-$9,360	25: $13,000-$18,000
In-hospital physician fees, including shunts & fistula fees	$1,800	$1,800	$3,000
TOTAL	$24,709 - $27,309	$28,826 - $31,425	$32,530 - $37,530

FIGURE 1 COMPARISON OF SUCCESS RATES OF DIFFERENT MODES OF DIALYSIS THERAPY.

PERCENTAGE OF PEOPLE REMAINING ON TREATENTS.



The University of Iowa
Iowa City, Iowa 52242

The University of Iowa Hospitals and Clinics
Office of the Director

(319) 356-1616

March 18, 1982

Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Subject: Senate Hearing on the Proposed
Prospective Reimbursement Rates
for the End Stage Renal Disease
Program; March 15, 1982

Dear Mr. Lighthizer:

We appreciate this opportunity to comment on the regulations proposed by the Health Care Financing Administration (HCFA) to implement section 1881 (b)(2)(B), added to Title XVIII of the Social Security Act by the Omnibus Budget Reconciliation Act of 1981. We are concerned that the proposed regulations will undermine the successes of the last decade in providing quality care to persons suffering from end-stage renal disease. In the following paragraphs, we outline a number of particular problems with the method HCFA proposes to utilize in establishing prospective reimbursement rates. We believe that, because of these problems, the proposed regulations fail to implement either the letter or the spirit of section 1881(b)(2)(B).

The regulations proposed on February 12, 1982, would significantly compromise the support of hospital-based programs that was clearly intended by the Omnibus Budget Reconciliation Act of 1981, which required that separate reimbursement rates be developed for hospital-based and independent dialysis facilities. In September, 1980, HCFA had stated that its data indicated that hospital labor costs averaged approximately 30% higher than independents and that other costs averaged approximately 13% higher. The initial rates under the new system proposed in February, 1982, however, would establish a reimbursement differential of less than 5%, while tightening the exception process under which hospitals had been obtaining some measure of relief.

HCFA's explanation for this minimal differential is that there is no justification for the higher labor and supplies cost. Regarding supplies, the supplemental information published with the proposed regulations includes the statement: "While the independent facilities may make greater use of volume purchasing, there is no reason to conclude that hospitals that fail to do so to a similar extent are operating efficiently." This completely ignores the fact that National Medical Care (NMC), the largest chain of independent dialysis centers, owns its supplier of dialysis supplies.

Regarding labor costs, HCFA has stated that the "data presently available to us through our medical information system do not support this claim" (that hospitals have higher labor costs because they treat sicker patients). HCFA has indicated that hospitals will have to justify higher labor costs through the exception process by demonstrating that they treat sicker patients. This approach places an impossible burden on hospitals, because an analysis of comparative severity of illness requires access to information regarding patients in both hospital and independent facility programs. HCFA has admitted that its own data regarding the patients of independent facilities is limited. Hospital-based facilities are in no position to acquire better data regarding independent facility patients. Thus, a policy requiring hospitals to prove that their ESRD patients are sicker than those treated by independent facilities is a policy designed to foreclose any consideration of this issue.

The most potent explanation of the cost differences between independent and hospital-based programs, and the strongest argument for the preservation and adequate support of hospital-based programs, relates to caseload. An independent facility, like a tertiary care center, requires a critical mass of patients in order to attain optimal cost efficiency. Independent facilities are located in large population centers where there are sufficient numbers of patients to operate on a multi-shift basis. Hospital-based facilities located in areas with low density population will never be able to provide dialysis at a unit price comparable to the high volume urban centers. Unless Congress adopts a policy requiring ESRD patients to move to major population centers (an outcome the Iowa satellite dialysis network is designed to avoid), there will continue to be a need for relatively less cost effective facilities to provide care to ESRD patients in geographic areas with low population density. An impact analysis prepared by ESRD Network #8, Inc., indicates that Network #8 (Iowa, Eastern Nebraska and Western Illinois), which has 1.2% of the nation's ESRD patients, would be forced to absorb 2.8% of the estimated "savings" to Medicare of the proposed reimbursement changes, despite the fact that this region has one of the nation's largest home dialysis programs.

The proposed regulations have made no adjustments to the underlying data to account for inflation, despite the fact that HCFA utilized data applicable to 1977-79 in developing the rates. HCFA rationalized this omission by pointing out that the number of facilities has increased since 1974 without adjustment of the screen. HCFA concludes that this increase must indicate that the industry is characterized by increasing efficiency. That conclusion disregards the exception process by which hospitals have obtained relief from cost pressures on the fixed screen. Even if the conclusion were valid, however, it would be specious to argue that the inflationary pressures generated since 1977 could reasonably be offset by increased efficiencies, especially in long-standing programs.

The regulations would also penalize hospitals, such as University Hospitals, for supporting strong home dialysis programs in the past. The 1981 legislation mandates HCFA to establish composite rates taking into account the mix of patients receiving dialysis at a facility or at home. Since a composite rate will necessarily be lower than the cost of outpatient dialysis and higher than the cost of home dialysis, it will be financially beneficial for the provider to encourage patients to dialyze at home. Based on the limited data it has acquired, however, HCFA has created two different ratios, one reflecting the percentage of home dialysis patients served by hospitals and one reflecting the percentage of home dialysis patients served by independent facilities. Because independent facilities have been less involved in home dialysis than hospital-based facilities, HCFA's approach, intended by Congress as an incentive for home dialysis, penalizes hospitals for their past involvement in home dialysis programs by factoring a higher percentage of lower cost home dialyses into the hospital composite rate.

Underlying all of the program changes designed to contain costs is an assumption that the setting in which dialysis is performed is a matter of medical indifference. That assumption is false. The End-Stage Renal Disease Program in the State of Iowa, because of Dr. Richard Freeman's strong support of home dialysis, is a microcosm of the system envisioned by the regulators, in which home dialysis is the method of choice. Even in University Hospitals' program, however, only 60 - 70% of the ESRD patients are dialyzed at home. The remaining patients are dialyzed on an outpatient basis because of overriding medical considerations (e.g., a severely compromised cardiovascular system) or because the patient does not have the social support system essential for successful home dialysis.

Summary

1. The regulations proposed by HCFA to implement the mandates of the Omnibus Budget Reconciliation Act of 1981 pay mere lip-service to the requirement that dual rates be established. HCFA has disregarded the historically higher labor and supply costs of hospital-based facilities and would require hospital-based facilities in low population density areas to provide care at costs comparable to high volume urban independent facilities.

2. HCFA has placed on hospitals the burden of proving that their patients are sicker than those of independent centers. Such proof, of course, is impossible without data concerning the independent facilities' patients, which is not available to hospitals.

3. Estimates by ESRD Network #8, Inc., indicate that facilities in this region would bear a disproportionate percentage of the total "savings" estimated by HCFA to result from these regulations.

4. The proposed rates are based on data applicable to 1977-79 without any adjustment for inflation.

5. By developing separate composite rates for independent and hospital-based facilities, HCFA is, in effect, proposing to penalize hospitals for supporting home dialysis in the past.

The University of Iowa Hospitals and Clinics fully supports the home dialysis program and the incentives mandated by the Omnibus Budget Reconciliation Act of 1981. We also understand the impetus toward a system of prospective reimbursement. We believe that the statutory language in the 1981 Omnibus Act should be sufficient to support the development of a reimbursement system that will equitably serve both urban and rural patients and encourage home dialysis when medically appropriate. We are concerned, however, that the regulations proposed by HCFA on February 12, 1982, would fail to implement an authentic dual rate system rationally based on the differing historical cost experience of hospital-based and independent facilities. If HCFA cannot be convinced to rework the proposed regulations to more accurately reflect the legislative mandate, further legislation may be necessary.

Thank you for the opportunity to express these views. If we may be of any assistance in your deliberations on these issues, please do not hesitate to contact us.

Sincerely,

Bill Hesson

William W. Hesson
Assistant to the Director

WWH:ssj

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Sheldon S. King
Executive Vice President and Director
Stanford University Hospital
Associate Vice President for Medical Affairs
Stanford University

March 19, 1982

Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Re: Senate Hearing on the Proposed Prospective Reimbursement Rates for the End Stage Renal Disease Program, March 15, 1982

Dear Mr. Lighthizer:

The proposed prospective reimbursement rates will clearly inflict financial hardship on many facilities. At Stanford University Hospital, the payment rate for chronic dialysis would be reduced from $240 per dialysis to $142, which will result in a loss of approximately $400,000 per year. Therefore, implementation of the proposal would pose very difficult decisions for many institutions, including Stanford. While we constantly seek to be more efficient, our costs would have to be reduced 50% to be below the proposed rate; we do not believe this to be possible. Thus, we would be faced with the alternative of discontinuing the service or raising rates in other areas to subsidize it.

In view of the potential damage to users and providers of dialysis services, a prospective reimbursement methodology should not be introduced unless it can convincingly be shown that it does in fact provide sufficient payments for efficient institutions. The proposed methodology does not do so. As published in the February 12 Federal Register, the proposal states that "we do not have a uniformly accepted, definitive model for a dialysis session. There are no uniform standards for the numbers and qualifications of personnel, or for staff-to-patient ratios, and the dialyses service seems to vary in intensity of care depending on the patient's health status." It continues, "we do not know whether as many patients of high-cost facilities actually require as high a level of care as indicated by costs." It admits that "the first step in setting the rate is to identify the legitimate costs of economically and efficiently operated facilities. One possibility would be to identify the particular facilities that we determined, upon inspection, to be economically and efficiently operated. This option is highly subjective and imposes great administrative burdens and therefore has not been used."

Instead the proposal sets the reimbursement level at "what appears to be an adequate level to reimburse an efficient and economically operated facility." Starting with median costs as representing an approximation of the cost of an efficient operation, the methodology makes a few very minor adjustments to account for legitimate differences in expense per treatment.

No adjusting factor is included for the most important difference among providers, the complexity of case mix. An exception process is made available to account such differences, but the regulation states, "we expect that under the proposal few facilities would be able to qualify for exceptions to their payment rates." Quotations in the paragraphs above demonstrate that the Health Care Financing Administration does not understand the reasons for cost differences among providers. Nevertheless, it has determined, in the absence of evidence, that the major reason is relative efficiency and that few facilities will be afforded relief by demonstrating a more complex case mix.

Another methodological difficulty is that no provision is made for cost inflation. As the study on which the methodology was based was conducted in March, 1980, and the cost data must have been at least one year old at that time, the target rates were set in dollars which have inflated for at least three years by 1982. In justifying the lack of an inflation factor, the proposal noted that although the current payment screen has been effective since 1974, the number of dialysis facilities has continued to grow (from 909 in 1978 to 1120 at present). Thus, it is inferred that efficiently operated facilities are not incurring suddenly rising costs. This fails to take a number of important points into account. First, although the current payment screen has not been adjusted since 1974, a relatively liberal exception mechanism has been in place which allowed effective payment rates to be increased with inflation. Second, the growth in dialysis facilities since 1978 has taken place almost exclusively in the independent provider sector (an increase of 70%) while the number of hospital providers has increased only 2.5%. Thus, HCFA must infer that independent facilities are the efficiently operated providers which are not incurring rising costs. One may as easily conclude that independent facilities treat a less complex and costly mix of patients and therefore thrive below the 1974 payment screen, while hospitals have encountered more difficulty in covering the costs of a more complex patient group with the current payment levels.

In summary, the proposed payment rates were developed using a methodology which is inadequate to the task. HCFA admits that it does not understand the nature of differences in cost among providers. It ignores the strong likelihood that cost differences may be explained by case mix complexity. Having failed adequately to identify payment rates which reflect efficient operations in terms of the mix of patients treated, HCFA has proposed to set a target rate which arbitrarily assumes that the median cost provider is an adequate standard for efficiency. HCFA provides an exception mechanism which has apparently been predetermined to result in little relief to providers although (again quoting the Federal Register) "if there were no exception process, this ... could result in dire consequences for beneficiaries if the proposed rate was insufficient to permit hospitals to continue furnishing dialysis services." Finally, in the face of economic reality, HCFA makes no provision for inflation in setting the payment rate.

The result is a payment rate which may penalize the efficient and reward the inefficient. It may well disturb service patterns and bring on serious consequences for beneficiaries. I strongly urge reconsideration of this proposal.

Sincerely,

Sheldon S. King

Sheldon S. King
Executive Vice President and Director

SSK:jtb

cc: AAMC Department of Teaching Hospitals

MMRF • MINNEAPOLIS MEDICAL RESEARCH FOUNDATION, INC.

REGIONAL KIDNEY DISEASE PROGRAM
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March 11, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, DC 20510

Re: Senate Hearing on the Proposed Prospective Reimbursement Rates for End-Stage Renal Disease Program

Dear Mr. Lighthizer:

Although there are numerous fiscal questions and comments which should appropriately be addressed relative to the proposed prospective reimbursement for dialysis services, I will restrict my comments to two major areas of concern which may negatively impact on the quality of patient care which would result should these proposed regulations be enacted. Our concerns relative to the financial problems with the proposed regulations are addressed in a letter to you from Mr. Gerald Gustafson who is the administrator of the Regional Kidney Disease Program and my associate. The first major concern that I have relative to quality of care pertains to the fact that the ideal home dialysis population is also the ideal transplant population. Programs which have in the past and currently continue to emphasize transplantation as the preferred modality of therapy, both medically and financially, will as a consequence of the new regulations be penalized. This results from the fact that active transplantation programs will minimize the potential pool of patients who can be successfully treated at home. This results in a lower proportion of patients who would otherwise be home if they did not receive renal transplants. As a consequence, the patients remaining on dialysis will be skewed toward either facility based dialysis or home dialysis with an assistant which are both more expensive therapies than self-care home dialysis. This could potentially lead to fewer patients receiving transplants in an attempt to preserve a more reasonable mix of patients on dialysis as the reimbursement level is insufficient to effectively compensate for the expenses of facility based or hired aide assisted home dialysis. I believe that it is essential that adequate consideration be given for more reasonable compensation in programs where transplantation is actively encouraged and performed as the patients who receive this form of therapy are also the ideal patients who could otherwise be treated with home dialysis.

Another major area of concern which is overlooked in the proposed regulations is the need to establish home programs in relatively small dialysis programs. The cost of establishing and maintaining a home dialysis program in which the utilization is relatively low is excessive. Currently, in our region, 5 out of 26 facilities have home dialysis training programs of which only 2 are sizable. Patients from the smaller facilities are generally trained at one of the two larger centers and continue to be followed by the larger centers. The institution of home training activities in the smaller somewhat remote units would be not only expensive to the units but would have to be performed without experienced personnel to train and operate a home program. This could severely jeopardize the quality of care which these patients would receive. If the major centers were to do the training and then refer the patients back to the smaller facilities for follow-up, there would be several problems associated with this. The first is that the centers are going to be reimbursed at a much lower rate than the true cost to do training as our own data suggest that our costs are in excess of $100 per treatment higher than the recommended level of reimbursement. Secondly, the smaller facilities do not have the trained personnel to provide the continuing services necessary to follow home patients. Therefore, I feel that it is totally inappropriate that the regulations should force all facilities to establish home programs through their reimbursement policies as this would be not only medically unwise but fiscally unsound for the smaller dialysis units.

These issues could potentially be resolved with an effective exception procedure. However, it is our experience that the time involved to have an exception request formally acted upon is excessive and the proposed regulations imply that very few exceptions would actually be granted. I do not believe that it is the intent of the proposed regulations to dramatically impact on quality of care, however, I believe that if they were to become operational, that either many of the smaller units will be forced to close or that the associated services necessary to perform quality dialytic therapy will be curtailed so severely that the net result will be a significant decrease in the quality of care which is being provided to these patients. I hope that you will consider these issues seriously prior to the enactment of the proposed regulations.

Sincerely yours,

Fred Shapiro

Fred L. Shapiro, M. D.
Professor of Medicine
and
Chief of Nephrology Section
Hennepin County Medical Center
and
Medical Director
Regional Kidney Disease Program

FLS/nlb

Statement
Proposed Prospective Reimbursement Rates for the End Stage Renal Disease Program
Hearing: March 15, 1982

The permanent, irreversible loss of kidney function is called end stage renal disease. At this stage of renal functional impairment, dialysis or transplantation is required to sustain the patient's life. Dialysis may be performed in the home or in a facility which is hospital-based or free-standing. A hospital-based facility provides a full spectrum of diagnostic, therapeutic and rehabilitative services; many of these hospital-based facilities also provide transplantation. A free-standing non-hospital-based facility provides only self-care training and chronic maintenance dialysis. Such units are required to have an affiliation agreement or arrangement with an approved hospital providing End Stage Renal Disease care.

The proposed new rates will have a dramatic impact on the patients, physicians, and facilities providing hospital-based care. The patients treated at hospital-based facilities are generally those patients with multiple medical problems including hepatitis who cannot receive adequate care at a free-standing facility. Many of these patients require the full spectrum of diagnostic, therapeutic, and rehabilitative services provided only at the hospital-based facility. In order to provide this array of essential services, the hospital-based facility is forced to have a larger professional component and advanced facilities to handle the complications which arise with this patient mix. A greater number of professional nurses versus technicians obviously costs the facility. The efforts to teach as many patients as possible to dialyze at home, again requires a larger number of professional staff. Although the initial treatment costs are indeed greater in a teaching hospital-based facility. the long-run overall expenses to the health system are diminished by having increased patients dialyzing at home. The proposed new rates will cause facilities to reduce staff to the point where home training cannot be done. Thus, all available dialysis stations in both the hospital-based and free-standing facilities will be occupied, forcing a decision to either build new facilities or to allow some patients to go without dialysis, which could result in irreversible harm to that patient. Physicians will be forced to determine whether they wish to continue providing care for patients in need of dialysis or go into another specialty area.

While a standard rate for equivalent care can indeed help reduce unnecessary costs of health care, we are not discussing equivalent care when we compare certain hospital-based facilities with free-standing dialysis facilities. A system of rate setting based upon the teaching component and results of that teaching could in actuality reduce health care costs. For example, a facility that is able to home-train successfully 25 percent of its dialysis patients could have the base facility rate, while those successfully training as many as 50 percent should have the highest facility set rate. This encourages facilities to maintain quality standards and at the same time encourages a less costly home dialysis. The base rate for home dialysis should in fact be the lowest established rate.

Executive Director
Presbyterian-University Hospital
Pittsburgh, Pennsylvania

NRAA
National Renal Administrators Association
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March 25, 1982

Senator David Durenberger
Chairman
Subcommittee on Health
Committee on Finance
United States Senate
Washington, D.C. 20510

RE: Subcommittee Hearings of March 15, 1982 Concerning the End Stage Renal Disease Program

Dear Senator Duremberger:

The National Renal Administrators Association (NRAA) requests the statements presented in this letter be entered into the record of the referenced hearings. We further request that your subcommittee give these issues every consideration in future congressional actions affecting the End Stage Renal Disease (ESRD) Program.

The NRAA is an organization of professionals involved in the day to day administration of hemodialysis and kidney transplant facilities. Our members are from both proprietary and non-profit facilities as well as hospital based and free standing units. Perhaps we are uniquely qualified to gauge the overall impact of the regulations presently under your purview because of our constant involvement with reimbursement issues, personnel staffing, and facility costs.

While we are continuing to gather data concerning the overall impact of the regulations from our membership and will forward additional information to you in the near future, we feel these major issues are the most obvious and should be brought to your attention as part of your current review process.

1. DO THE PROPOSED REGULATIONS COMPLY WITH CONGRESSIONAL INTENT?

> We think not. The Congress directed the Administration to develop separate rates for hospital based and independent facilities. The proposed rates were developed using a methodology applicable only to independent facilities and were simply increased for hospitals based on what the Health Care Financing Administration (HCFA) felt were the only real distinctions between these two varying types of treatment centers.
>
> For instance, the data shows that hospital based facilities have a $20 higher labor cost than indepen-

dent facilities. Why should that differential not be allowed in the composite rate structure?

In addition, HCFA has pointed out the fact that, on average, hospital have fewer "stations" than independent facilities. Simple arithmetic proves that the costs are higher in these facilities because the cost of fixed overheard is reduced when more "stations" are employed.

2. DOES THE PROPOSED COMPOSITE RATE STRUCTURE ENCOURAGE A SHIFT FROM OUTPATIENT DIALYSIS TO HOME DIALYSIS?

No! In fact, these regulations, much like those which were illconceived and poorly written in 1973, will penalize both patients and centers who would have otherwise opted for home dialysis. It was the 1973 regulations which almost destroyed the home dialysis program entirely. We fear these new regulations will have a similar impact on the gains we have made since 1978.

First of all, $20 for home training is unrealistic. Training for home dialysis is a labor intense exercise which requires high concentrations of highly skilled and highly paid licensed personnel. According to a HCFA report dated December 29, 1981, the average cost of a home training session was $226. The great majority of facilities will not be able to make the sizable cash investment in home training required to effectively promote this modality of treatment.

With the removal of the 100% Reimbursement Agreement for equipment and supplies, there is no longer an incentive for patients to opt for home dialysis. They will now have to pay for 20% of all aquisition, maintenence, and water treatment through the composite rate.

Next comes the cost of the equipment. Facilities will be required to make a $7,000 to $9,000 investment in equipment in the hope that a patient will become a viable long-term home patient. It will take four to five years for most facilities to recoup the initial capital outlay. How many facilities do you suppose will be able to make these sizable expenditures in any quantity? What will be the cost of financing? What prudent businessman or administrator would pursue such an investment in times such as these, especially when "return on equity" is no longer being considered an allowable cost factor? Will these investments be made in light of the stated intent to lower the rates even more in the future?

The only reason the present home dialysis equipment pool has not been utilized to its potential is because the program is a complicated morass of red tape and has not been properly presented or explained to the dialysis community. Were the program streamlined and made accessible to the majority of the facilities, it would be better utilized and probably highly successful.

One facility reported to us that their model home program would be all but destroyed. This is especially destructive since their average distance from patient to center is 112 miles. Hence, a three hour treatment becomes a seven hour ordeal. Contrary to the assertion made in Appendix I of the rules, patients and families will not benefit in a reduction of travel and expenses in many cases.

3. IS THE DELETION OF "RETURN ON EQUITY" AS AN ALLOWABLE COST GOING TO RESTRICT EXPANSION, REINVESTMENT, RESEARCH AND DEVELOPMENT?

We believe so. Return on Equity is an acceptable cost of doing business just like labor, equipment, and facility costs. If rates are going to be continually readjusted to reflect cost without consideration for return on equity a serious precedent will be set. This precendent might deter the future entry of proprietors into the healthcare field.

One of the major manufacturers of dialysis equipment recently stated during a presentation to our association that they had closed their research and development department because their "return on equity" was not adequate to fund further research. Should teaching hospitals and research facilities follow as a result of these regulations, the true answer to the spiraling cost of the ESRD Program will never be found - that answer being a simpler, more cost effective treatment modality.

In fact, the present program, whose cost per treatment has not increased since the program's inception, will probably be caught up in the inflationary spiral of other medical care costs. It is the expansion of facilities and the improvement in methods of treatment which have kept the reimbursement rates constant since the program began.

For any health facility it is return on equity which insures its ability to continue its operation long into future. Can you imagine the dilemma a facility will face when they take their financial statement to their bank to finance home dialysis equipment and are asked, "Where is your Return On Equity?"

4. CAN THE ADMINISTRATION EXPECT TO BE SUCCESSFUL IN SAVING THE PROJECTED $130 MILLION?

Yes. It almost seems that the approach utilized was to take the savings projected by the Office of Management & Budget and develop a composite rate methodology that would achieve that goal. This is commendable until we look at the certain impact of that methodology:

a. 100% of the facilities we've queried on the issue stated that the first reduction in their facilities' costs would be in staff to patient ratios. Major reductions will have to be made in nursing staff resulting in less supervision of technicians. Ask any patient if their facility is overstaffed with nurses.

b. Those proprietary independent facilities which are unable to launch an effective home care placement and training program and unable to recoup their costs from in-center dialysis will be forced with closure or to dangerously jeopardize quality of care. Both of these are unacceptable alternatives.

If, in fact, HCFA is attempting to control costs by limiting access to care or restricting quality of care, we submit that it is inappropriate. Only the elected representatives of the people, the Congress, should have the power to determine who will receive care and who will not. It should certainly not rest with government personnel not accountable to the people.

RECOMMENDATIONS

1. The HCFA should update and insure reliability of its three year old data base for both hospitals and independent facilities before setting the composite rates.

2. That separate rates be developed for hospitals and independent facilities based on their separate costs as intended by the Congress.

3. That the composite rate for home dialysis be reduced by $20, and 100% reimbursement be continued for equipment, maintenance and supplies as an incentive for patients to dialyze at home and for facilities to send them home. Facilities would not be required to make the sizable cash investment required. Thus, the incentives for home dialysis would be maximized and future program savings would be realized.

4. That the present authorized allowances for home training be accepted. In the absence of this revision, most facilities will either delay or not begin home dialysis training until the allowed costs are increased.

5. That the Home Dialysis Equipment Pool be retained and that organizations such as ours be used as information resources for the pool.

6. That a reasonable "Return on Equity" in the range of 15% be allowed to encourage reinvestment, research and development.

7. That patient rehabilitation models be established as pilot projects to determine the cost/benefit of rehabilitation and act as a guide for all facilities.

SUMMARY

The National Renal Administrators Association cannot support the so-called profiteering that is alleged to exist in the ESRD Program. On the other hand, the harm that will be done to the patients and facilities who have tried to work with the Program cannot be justified in the name of eliminating the "fat".

The sole reason fair reimbursement mechanisms have not been established is found in HCFA's inability over the past nine years to establish a reliable data collection system. We will never be able to tell where the Program is going until we know where the Program is.

Our request to you, your Committee and the Congress is to intervene in the promulgation of these regulations until all of these issues, as well as many others, are addressed. We are concerned that, short of this intervention, the rules will take effect on May 1, 1982 without regard to the public comment.

Thank you for your time and consideration on behalf of the NRAA and the patients and facilities who depend on us.

Respectfully submitted,

NATIONAL RENAL ADMINISTRATORS ASSOCIATION

John Warner

JOHN WARNER, Director
Governmental Affairs

cc: NRAA Board of Directors
Terry L. Schmidt, Inc., Health Care Reimbursement Consultants

JW:drb

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March 25, 1982

Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Re: Senate Hearing on the Proposed Prospective Reimbursement Rates for the End Stage Renal Disease Program

Dear Mr. Lighthizer:

The following comments and observations are made as a result of the proposed prospective reimbursement rates for the End Stage Renal Disease Program published in the Federal Register on February 12, 1982. We bring these observations and comments to your attention because of the controversial nature of the proposed rates which in many cases are translated into inappropriate and inadequate reimbursement for the facilities providing these services.

With regards to the adequacy of the data on which the Administration based the new rates, it should be noted that the option chosen, i.e., the composite rates for home and in-facility dialysis is based on median cost of all facilities. It is acknowledged in the regulation that these rates would result in reimbursing 46% of all hospital-based facilities and 28% of all independent facilities at a rate per treatment below their current costs for in-facility dialysis. Several issues should be raised in regard to this principle. For a start-up facility it is generally acknowledged that the rates per patient during the initial year of operation is higher than a facility which has reached capacity. This is generally the case in that the fixed costs of operating the facility must be spread across a smaller patient base. Also, it should be noted that a facility that provides services to the medically indigent, as a county hospital district is charged with doing, generally has a population with a higher incidence of ESRD, which is typically found among minority populations. Further, a facility that provides services such as transplant services would have a patient mix represented by patients with more intensive or acute problems. In this regards, the average costs far exceed the median costs for all hospital-based facilities.

The hospital labor rate was based on an average for all hospitals; the labor rate in a dialysis facility is skewed with a higher proportion of skilled labor to unskilled, than a general hospital facility. Therefore, average labor rate is understated.

The final HCFA audit included 67 hospital based facilities out of 537 total hospital-based facilities at the time of the audit. There is no mention of the average size, location, or type of facility included in the sample and therefore inappropriate biases may be present.

The report in the Federal Register makes reference to cost adjustments for supplies in the hospital-based facility. The new rates assume that hospitals and independent facilities can buy supplies at the same rate. While this assumption may not be totally incorrect, there was no review to determine whether or not hospital-based facilities actually use more supplies than independent facilities. The rate setting methodology only examines cost effectiveness - there was no analysis as to the recommended level of patient care.

While the proposed regulations do take into account local wage index differences, there was no mention of shift differential pay for hospital-based facilities that must operate at least two shifts in an outpatient dialysis center.

The rationale that an increased number of dialysis facilities indicates operating efficiency and that the only inflation factor for the limitation should be 105% of the median costs does not work for hospital-based facilities. While the costs for outpatient dialysis may not have increased significantly in recent years, the total operating costs of a hospital-based facility far exceed the 105% add-on based on cost reports for 1977, 1978, and 1979.

In the event of a first year hospital-based facility being subject to the dialysis limitation, it would be reasonable to assume that there would be a certain period when all dialysis treatments would be performed in the facility. The only additional add-on for home dialysis training is $20 per session. There was no study mentioned in determining whether this additional amount was reasonable. These efforts are clearly "cost containment" oriented without regard for quality of care and patient outcome. In "great" Britain it is estimated that 3 to 8 thousand patients die yearly from ESRD because of inadequate numbers of dialysis facilities. I am sure this is cheaper but it can not be confused with cost-effectiveness for that term must be balanced by bioethical standards which can not be compromised without an affront to human worth and dignity.

Sincerely,

Ron Anderson MD

Ron J. Anderson, M.D.
Chief Executive Officer

cc: Richard M. Knapp, Ph.D.
Director, Dept. of Teaching Hospitals
Association of American Medical Colleges

kc

University of Pittsburgh
SCHOOL OF MEDICINE
Department of Medicine
Renal-Electrolyte Division

March 25, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Lighthizer:

This letter is written with regard to the Senate hearing on the proposed prospective reimbursement rates for the end stage renal disease program held on March 15th, 1982. I want to address the effect that the reimbursement schedule would have on our patient population. We face a similar problem to that of other University Hospitals. That is to say, that our patients generally represent those with the most numerous and severe complications of their end stage renal disease. They gravitate to our service as a result of the fact that they require a great deal of attention, making them poor candidates for free standing dialysis units in which, to keep costs down, staff to patient ratios are low. Furthermore, because of the emphasis that we and other teaching hospitals place on self care and limited care dialysis, as well as home training, we are not able to process patients as rapidly as free standing units. Furthermore, our requirement to provide training for physicians, nurses and paramedical personnel restricts our ability to reduce our costs even to the current screen, much less to the proposed levels.

In consequence of these considerations, it is my impression that should the prospective reimbursement rates be established, the result would be a deleterious effect on our end stage renal failure program at the University of Pittsburgh School of Medicine. It would have the effect, I am sure, of denying care to those people most in need of it. Therefore, I urge the Subcommittee on Health to oppose any further restriction of funding for the end stage renal disease program. In human terms, the adoption of these rates would be disastrous, in my opinion.

Sincerely yours,

Jules B. Puschett, M.D.
Professor of Medicine
Director, Renal-Electrolyte Division

JBP/mmp

March 22, 1982

Robert E. Lighthizer
Chief Counsel
Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20610

Dear Mr. Lighthizer:

The End Stage Renal Disease (ESRD) Networks are among the many programs scheduled to be eliminated in the 1983 Budget Proposal. Although my position as a staff member of ESRD Network 15 may prejudice my opinion, I feel it is my duty as a taxpayer to voice my feelings on this subject.

Networks have been the responsibility of the Health Care Financing Administration (HCFA) since their inception in 1978 (P.L. 95-292). In the past four years, Networks have established themselves as a viable part of the renal community, and a valuable source of data essential to the medical community. The Networks involve not only physicians, but also nurses, social workers, dieticians, and patients, creating a unique mix that truly reflects the patients' needs. In January of 1981, Networks became responsible for the collection of all non-reimbursement data forms from the renal units due to the fact that HCFA's Medical Information System (MIS) failed miserably in this attempt. I have been with the Network 15 office for four years, and have witnessed its growth in responsibilities and accomplishments.

Networks have certainly proven themselves to HCFA, yet unfortunately our "parent" organization (HCFA) has not carried this further. Congress has received no information on Networks for two years. The 1981 Annual Report to Congress is a year late, and has been rewritten to include very little information on Networks. HCFA has not even input the data Networks have forwarded to them into their own MIS. Unfortunately, the only data available to Congress is what HCFA gives them. What HCFA is giving Congress is their proposal not to fund Networks in 1983.

I question the fairness of this process. Are Networks considered guilty until proven innocent? How are organizations such as Networks heard when their "parent" organization such as HCFA presents inadequate information? Hopefully, the answer to this question is through their Congressmen and I urge your support.

Sincerely yours,

Deborah W. Peters

Deborah W. Peters
209 East Lake Drive
Springfield, IL 62707

W. TOM MEREDITH, M.D., P.A.

ST. FRANCIS MEDICAL PARK BUILDING
1035 N. EMPORIA, SUITE 105
WICHITA, KANSAS 67214-2998

PHONE (316) 263-7285
AFTER HOURS 262-6262

March 23, 1982

Proposed Changes As Outlined in Federal Register
Friday, February 12, 1982

Concerning: Medicare Program; End-Stage Renal Disease Program; Prospective Reimbursement for Dialysis Services (BPP-126-P)

Hearing: March 15, 1982

PREFACE:

St. Francis Hospital Dialysis Center in Wichita, Kansas agrees with many parts of the proposed rule concerning the federal end-stage renal disease program.

For example, this Center strongly supports the promotion of home dialysis whenever it can be used without jeopardizing the patient's health and well-being. Accordingly, the St. Francis Hospital Dialysis Center has 25 to 30 percent of its dialysis patients on home dialysis. Our percentage is considerably higher than the national average of 17 percent, which was reported in the Federal Register of February 12, 1982. In fact, only five or six states have as high a percentage of home dialysis patients as the state of Kansas. In addition, it should be noted that the Federal Register states that only 30 to 40 percent of the dialysis population can safely dialyze at home.

The Federal Register indicates that centers with a higher home dialysis percentage will have an advantage under the prospective reimbursement for dialysis services. However, despite this advantage, the St. Francis Hospital Dialysis Center will still have major problems meeting the new cost restrictions unless considerations are made in implementing the proposed rules.

We ask that strong consideration be given to the following recommendations before final enactment of the proposed rules:

1) Delay implementation of BPP-126-P by three to six months to give centers the staff time needed to make necessary adjustments. These adjustments include training patients to become more involved in their own dialysis.

The Health Care Financing Administration (HCFA) could take this same time to review the costs they used in developing the proposed rules. An audit of the St. Francis Hospital Dialysis Center was part of the information used to arrive at the prospective reimbursement rates. The audit was based on cost data of 1980. Since the time of the audit, the financial base of the St. Francis Hospital Dialysis Center has changed considerably. Labor, just one component of our dialysis cost, has increased 20 percent. In addition, there have been increased costs in relation to the shipment of supplies and indirect costs such as utilities.

It should be pointed out that in-hospital centers cannot separate salaries of dialysis nurses and personnel from those in other parts of the hospital or the community. To be able to maintain a well-trained dialysis staff and to attract new employees, it is necessary to offer those individuals the same wages they can obtain in similar positions in other service areas not under the cost restrictions proposed for dialysis centers.

2) The proposed rules offer enough cost containment that prior restrictions in earlier rules are no longer necessary and are, in effect, redundant. Prior restrictions should be removed from BPP-126-P. The restrictions on utilization rates are a good example. If centers can accomplish dialysis more cost effectively by utilizing more machines or by performing dialysis treatments in three days a week rather than in six days, they should be encouraged to do so. Under the proposed rule, this cost containment would be hampered by pre-existing rules and regulations.

The labor cost component of dialysis has increased more rapidly than have costs of supplies or machines. Portions of the labor cost could be eliminated by running extra machines and extra stations. For example, the St. Francis Dialysis Center will soon take over operation of the Dodge City (Kansas) Dialysis Unit, which has a limited number of rural patients. Cost studies have shown that the Dodge City unit could be more economically operated by running eight machines three days a week rather than four machines six days a week. However, current restrictions limit the number of machines to four. If this prior restriction is retained, the Dodge City Dialysis Center could possibly be forced to close. The majority of Dodge City patients are quite elderly and have no other dialysis treatment available to them.

To change the current utilization rate requires a lengthy, costly process involving networks and Health Systems Agencies. The solution is to remove these prior restrictions from BPP-126-P.

3) The intermediary in this area is already misinterpreting the proposed regulations. We recommend that intermediaries, such as Blue Cross and Blue Shield, be given the opportunity to develop a clear understanding of the rules before the rules are implemented. It is our understanding that the purpose of the prospective reimbursement for dialysis services is to allow centers to make a certain profit on home dialysis. This profit can be used to off-set losses on in-center dialysis. The local intermediary, however, interprets the regulations to say that no profit can be made on home dialysis and that home dialysis will only be reimbursed at cost.

It should also be mentioned that maintenance of separate cost centers for in-center dialysis and home dialysis creates redundant paperwork and adds to dialysis cost.

4) Another difficulty with the proposed rules is that they would virtually eliminate development of any new rural dialysis centers in Kansas. Kansas already has an extremely limited number of dialysis centers. Today, people with end-stage renal disease who live in northwestern Kansas communities such as Goodland, Russell, and Hays are 200 miles from dialysis therapy. The patients in these areas who are able to use home dialysis modalities are currently doing so. The people who can't use home dialysis must either travel long distances for dialysis therapy or up-root themselves from lifelong homes and move to a strange community that offers dialysis treatment.

The new rules, particularly those for rural reimbursement, would severely limit the development of centers in northwestern and southwestern Kansas. The new rules contain no exceptions for start-up costs and the rigid restrictions on reimbursement would make it difficult to obtain appropriate staff and physicians for a new center.

5) Recruitment of physicians and qualified personnel would be hindered by the new cost restrictions. It is my opinion that this will lead to fewer nephrologists taking care of more patients - which would effectively decrease the level of care. The cost restrictions would also hinder competition for qualified nurses and other personnel, who would be tempted to work in service areas which don't have cost restrictions and, therefore, have higher salaries.

6) Our patients are developing a "locked-in" syndrome. Many centers around the country that previously accepted St. Francis Hospital patients for treatments during their travels are no longer able to help them because of restrictions and cost containment problems. There are patients who are no longer able to travel to other parts of the country for funerals, weddings, or business. This is making the patient who can't use home dialysis feel like a leper as far as traveling is concerned. The Federal Register states that only 30 to 40 percent of the dialysis population can safely dialyze at home. This means that at least 60 percent of the dialysis population is being more and more restricted in their ability to travel.

In closing, we emphasize that the regulations do have many positive aspects. However, the St. Francis Hospital Dialysis Center feels that time is needed to rectify the above concerns and to help the patients adjust to the new proposals. None of us want to leave the renal dialysis patients to the mercy of regulations. It is the contention of this Center that dialysis patients should not be treated as "second class citizens". Further restrictions on their ability to cope with the devastating effects of their renal disease should not be imposed.

W. Tom Meredith, M.D.
Medical Director, Dialysis Unit
St. Francis Hospital

Center for Health Sciences
University of Wisconsin-Madison
University Hospital and Clinics

600 Highland Avenue
Madison, Wisconsin 53792

March 24, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, DC 20510

Dear Mr. Lighthizer:

Subject: Senate Hearing on the Proposed Prospective Reimbursement Rates for the End-Stage Renal Disease Program

The University of Wisconsin Hospital and Clinics is presenting the following comments on the issues outlined in the COTH General Membership Memorandum #82-3, dated March 5, 1982:

ISSUE 1. Adequacy of data base to derive proposed rates

It is questionable whether the degree of complexity and variability of hospital facilities providing dialysis services was considered when arriving at a methodology and choosing a sample.

Hospitals provide the level of care relative to community and environmental needs of their patients. There are no definitive standards to apply in determining whether or not a facility is operating efficiently and economically. The sample, while being statistically significant, could produce a median or other data irrelevant to the question of efficiency. Other factors such as the diagnostic mix of patients were not included as a cost-related variable.

ISSUE 2. Adequacy of rate setting method

The rate method proposed is inconsistent with the determination of all operating costs of a hospital-based facility. As explained in the Federal Register, February 12, 1982, reasonable costs were determined by the Medicare principles of provider reimbursement. Therefore, the costs arrived at by each hospital are already reasonable as determined by Medicare. The median cost was approximately $135 within a range of $86 to $277. The range of cost per treatment questions the median as being a significant benchmark to use in setting a rate.

The deficit which University Hospital and Clinics would incur at a rate of $132 could cause a serious crisis. If we maintain the dialysis service at the present level we would have to increase our rates in other services to maintain our nursing and technician staff for the dialysis service. It seems as if we are being forced to reduce our reasonable costs further to meet governmental constraints. The primary purpose of our mission is to foster a public health program designed to reduce morbidity and mortality as well as the economic burden caused by kidney disease.

ISSUE 3. Provider adaptation to new rates

If rates are set prospectively at or near $132, hospitals will have to seriously consider abandonment of the program. This would certainly not be in the best interest of our community. It would be very difficult for providers whose reasonable cost is greater than the median national coverage to absorb this deficit.

ISSUE 4. The potential effect of new rates on patients, physicians, and facilities

University Hospital and Clinics is a tertiary care center which has a patient mix including a large number of high risk patients. Experience shows that our patients could not be accommodated in a non-hospital based facility because of these complicating factors. We recently completed a study involving all outpatient renal patients. We found that in addition to the primary diagnosis of renal failure on the average these patients have six secondary diagnoses. Most common of these are: diabetes with peripheral circulatory disorders, malignant neoplasms, rheumatic heart disease, primary pulmonary hypertension, cardiovascular disease, angina pectoris, pulmonary congestion and hypotosis, etc. These patients obviously require a higher level of care.

Sincerely,

Peter H. Christman
Acting Director of Finance

PHC:cc

COUNCIL OF TEACHING HOSPITALS
ASSOCIATION OF AMERICAN MEDICAL COLLEGES

Suite 200/One Dupont Circle, N.W./Washington, D.C. 20036/(202) 828-0490

COTH GENERAL MEMBERSHIP MEMORANDUM
#82-3
March 5, 1982

SUBJECT: Senate Hearing on the Proposed Prospective Reimbursement Rates for the End Stage Renal Disease Program

Senator Dave Durenberger (R-MN), Chairman of the Subcommittee on Health of the Committee on Finance announced that the Subcommittee will hold a hearing on Monday, March 15 to review the proposed prospective reimbursement rates for the end stage renal disease (ESRD) program which were published in the Federal Register on February 12, 1982. Specifically, the Subcommittee expects to hear testimony at the March 15 hearing which addresses:

- the adequacy of the data on which the administration based the new rates;
- the adequacy of the rate setting methodology;
- the ability of providers to adapt to the new rates;
- the potential effect the new rates will have on patients, physicians and facilities.

If you have observations, suggestions or criticisms on any of these four issues, I urge you to submit written testimony to the Subcommittee. The difference in the rate for hospital based free standing programs has been and continues to be controversial. If you have data which contrasts the characteristics of patients served in hospital based programs as opposed to free standing programs, the Subcommittee would be most interested in receiving and reviewing this data.

The Subcommittee encourages the submission of written statements for the record. These statements (five copies should be mailed) should be received by the Subcommittee no later than March 26, and should be addressed to:

RECEIVED
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SUPERINTENDENT

Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, DC 20510

On the first page of your written statement, please indicate the date and subject of the hearing. If you submit a statement, please send a copy to the AAMC Department of Teaching Hospitals.

RICHARD M. KNAPP, PhD
Director
Department of Teaching Hospitals

THE FORUM OF END-STAGE RENAL DISEASE NETWORKS

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April 2, 1982

Mr. Robert E. Lightizer
Chief Counsel, Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lightizer:

On behalf of the Forum of ESRD Networks, I am submitting this written statement for inclusion in the printed record of the Senate Finance Health Subcommittee's hearing of March 15, 1982 relative to:

> The proposed Prospective Reimbursement Rates
> for the End-Stage Renal Disease Program

Although the Subcommittee heard testimony on network activities in September 1981, this statement specifically addresses the proposed regulations and the relationship of networks relative to their proper administration and evaluation.

The Health Care Financing Administration's (HCFA) proposal for implementing Congress' mandated dual composite rate structure will have an immediate impact on the majority of ESRD facilities in this country. How the providers of care will adjust to these new rates is not fully understood.

Congress has the responsibility for evaluating these changes and their impact on patient care.

Networks are the only mechanism currently in place which have the data and professional expertise necessary to assist Congress in assuring that renal patients are not adversely or unjustly penalized as a result of these Congressional and Administrative changes in the reimbursement policy. It is unfortunate that HCFA has recommended the elimination of networks at a time when their functions are absolutely critical to the continued health and safety of over 68,000 renal patients.

Members of Congress have been reviewing carefully the total ESRD program in order to determine the most effective mechanism for controlling costs without endangering the quality and appropriateness of care delivered to ESRD patients. While a consensus exists relative to the soundness of this objective, there is strong disagreement with respect to the most appropriate mechanism. Previous public laws and regulations aimed at encouraging less expensive treatment modalities have not been successful. The current proposed regulations have been met with criticism and fear by both providers and patients. The Forum believes that Congress is forced by HCFA to formulate legislation without the benefit of complete, accurate and timely ESRD data, the absence of which is referenced throughout the proposed regulations and emphasized by those who criticize them. The Forum asks that the Subcommittee give careful consideration to the critical need for accurate data, the historical inability of the national ESRD - Medical Information (MIS) to provide such data, and the current role of networks in data-related activities.

The national ESRD-MIS, plagued with problems since the onset of the program, has been for nearly a decade unable to produce the data necessary for proper program management and administrative decision making. When networks were funded in 1978, they were told that the MIS would support their data needs relative to the performance of their required medical review functions. Recognizing that medical review without data is impossible, networks independently, and often in conflict with HCFA directives, developed their own manual patient data collection systems. It was, in fact, the access to data at the network level that led to identification of specific problems in the MIS. As a result, effective January 1, 1981, HCFA assigned to networks full responsibility for the collection, validation and submission of all non-reimbursement MIS forms. This was in addition to their responsibility for the Semi-Annual MIS Facility Survey and the MIS Patient Census. Just last year HCFA permitted networks to establish access to computerized data processing. Since that time the majority of networks have converted from manual to automated data systems.

In previous Congressional testimony, the Forum stated that if networks were continued in 1982 they would be able to provide data that characterize the dialysis and transplant patient population. Last week, Forum representatives presented samples of such data to your staff for review. Information available at the network level includes socio-demographic characteristics, morbidity factors, and incidence, prevalence, and mortality rates. Unfortunately, the ESRD-MIS has not provided comparable data for the nation, even though networks have met their responsibility relative to the collection and submission of MIS forms. The Forum regrets that HCFA has made no effort to coordinate data activities between networks, nor have they requested our reports for your review. All activities now underway relative to providing a meaningful exchange and sharing of information between networks has been initiated by individual networks and coordinated via the Forum. The Forum itself was organized voluntarily by network chairpersons to meet this need for communication between networks.

Patients and providers have expressed their concerns relative to HCFA's plan for monitoring the impact of the proposed regulations on the quality of care rendered to patients. Serious questions have been raised as to what measures are planned to assure that appropriate care is provided in a fair and equitable manner. Senator Durenberger articulated these concerns when he stated that:

> "renal patients will not be allowed to suffer or perish because of the proposed rates..."
>
> "...facilities will not be allowed to exclude or reject older or seriously ill patients..."
>
> "...and physicians will not be allowed to inappropriately place patients on home dialysis in order to take advantage of the monetary incentives provided in the new rates if these patients are not medically, socially, and psychologically suited to home care."

Networks and their Medical Review Boards (MRBs) represent the only mechanism ready to respond to Senator Durenburger's well stated concerns. Since 1978, MRBs nationwide have performed activities relative to their regulatory functions, which are summarized below: (See Section 405.2113, Federal Register, June 6, 1976):

- Monitoring and assessing the appropriateness of patients for the proposed treatment modalities
- Evaluating the performance of facilities and physicians based on aggregate data for at least the following three areas: appropriateness of the proposed treatment modality; morbidity; and mortality
- Performing medical care evaluation studies, which include the development of criteria and standards, data collection and display, interpretation of the findings, institution of corrective action, and reperformance of any study which includes a problem
- Performing in-depth studies as indicated
- Offering recommendations for improvements and reporting inappropriate or substandard care to the Secretary.

Medical Review Boards have met their responsibilities relative to these functions. The majority of networks have conducted studies on the appropriate selection of patients for home dialysis, and can update these studies as necessary. Criteria sets and the results of these studies are available for your review at any time. The range of topics selected by networks for indepth study is impressive. The Forum has compiled a listing (attached) of these studies and other related activities performed by networks during 1981.

HCFA has stated that "continuous ambulatory peritoneal dialysis (CAPD) is the preferred treatment for many patients." Currently, there is no medical evidence to support this position as long-term clinical experience is just beginning. In addition, data are not available to support a conclusion that CAPD is a less costly treatment option. Although networks do not collect actual cost data, they are conducting studies which will help determine how this treatment modality compares to other forms of dialysis in medical effectiveness and cost by taking into account the rate and duration of hospitalization. This is but one example of how networks simultaneously evaluate the effectiveness of care and associated costs.

HCFA is required to report annually to Congress on the total ESRD program, including the role of networks. In order to prepare this report, HCFA requires networks to submit an annual report documenting all activities. Unfortunately, network achievements have, for the most part, been omitted from HCFA's report to Congress.

Members of the Forum have had the opportunity to review the draft copy of HCFA's 1980 ESRD Report to Congress and compare it to the final document. During the revision process, HCFA omitted key sentences including the following on the role of networks relative to data:

> "The efforts (networks role in collecting and submitting MIS forms) culminated in 100 percent compliance in Facility Survey forms, resulting in increased validity and accuracy of the ESRD patient data base."
>
> "The data (collected by networks for their individual patient data systems) supplement the national MIS data, making possible profile analysis on an individual network basis in areas such as incidence, prevalence and survival rates by treatment modality, age/sex distribution of patients, primary diagnosis statistics, and facility capacity reports."

Because the Forum believes that Congress is not receiving from HCFA an adequate or honest summary of network achievements, we are preparing our own 1981 Annual Report on Network Achievements, which will be ready for distribution by late April. We feel confident that you will be impressed by its content, and as puzzled as we are when you compare it to reports from HCFA.

Recently, Dr. Carolyne Davis, Administrator of HCFA, was asked to testify on the ESRD Program before a Subcommittee of the House Government Operations Committee. When asked how HCFA monitored the quality of care, she responded that this was the function of networks. She was then asked if HCFA had recommended the elimination of networks, and she responded yes. When asked why HCFA recommended the elimination of networks, she stated because (1) the networks had not shown that they were successful enough to warrant their cost, and (2) the networks' planning role is hampered by the individuals' conflicts of interest. These reasons clearly demonstrate HCFA's lack of understanding of the network program. First, the total network budget for 1982 was $4.5 million, or less than .3% of the estimated $1.8 billion total annual ESRD program budget. Considering network achievements relative to data collection, validation and application for assuring the quality of patient care, it seems unreasonable to recommend the elimination of networks for reasons of cost. Secondly, networks have never had any authority relative to the planning process. Networks provide information, such as incidence and prevalence data, to those local and regional agencies legally responsible for health planning. The Forum believes Dr. Davis has misled Congress as to the functions and cost-effectiveness of the network program.

In conclusion, networks comprise a relatively inexpensive, functioning system that has already demonstrated the ability to generate meaningful data impacting on the quality of care, cost control, and the effective administration of the total program. No other system exists for carrying out these functions and the interruption of network activities would prove disastrous to the management of the ESRD program.

The Forum urges your thoughtful consideration of this statement as you review comments submitted by those who are concerned as to the impact of the proposed regulations on the patients with end-stage renal disease. We are optimistic that you will recommend denial of HCFA's proposal to eliminate networks.

If you have any questions or wish to review documents cited in this statement, please feel free to contact me.

Sincerely,

D. E. Gentile

Dominick E. Gentile, M.D.
Chairman, Forum of ESRD Networks

Attachment

DEG:eq

END STAGE RENAL DISEASE PROGRAM

HIGHLIGHTS OF 1981 ACTIVITIES OF THE NETWORK COORDINATING COUNCILS

Prepared by the Forum of End Stage Renal Disease Networks

HOME DIALYSIS AND TRANSPLANTATION

All Networks have placed a major emphasis on the encouraging of home dialysis or transplantation for those patients who are medically and psychologically suited for these modalities of treatment. The approach and method utilized by the Networks are diverse. The following highlights reflect the Networks' knowledge and investigation into this complex issue:

- developmental criteria fo identify and evaluate candidates for home dialysis or transplantation;
- data analysis on mortality and morbidity associated with home dialysis or transplantation;
- training programs and development of standardized long term patient care plans;
- development of educational materials for patients and facility staff such as: seminars, workshops, booklets, posters;
- profile analysis of patient characteristics by modality of treatment; and
- working with other agencies to heighten hospital and public awareness of the need to increase organ procurement.

DATA ACTIVITY

All Networks have established either manual or computerized data systems for use in reporting ESRD activity to MIS. Two-thirds of the Networks have established computerized data systems. The following activities and projects were completed by the Networks in the area of data management:

- establishment of a baseline patient-specific data system in each Network; some sophistication exists in Networks with computerized data programs;
- collection and validation of patient specific data reported on MIS non-reimbursement forms and the MIS 6-month facility survey forms;
- use of data to assist in ESRD application review process by local and regional agencies. These agencies use Network data as a basis for the utilization review and certificate of need process. The data reflects current need, utilization, and resource availability. The data is also distributed to the providers of care in the Networks;
- the established patient-specific data bases have increase accuracy of reporting data as well as promotion of timely submission of MIS forms;
- use of the data system to update and correct MIS data (verification) reports and to identify "unknown" patients reported by MIS;
- development of profile analysis of patient populations;
- development of studies and statistics on mortality and morbidity, incidence and prevalence, transplantation and home activity;
- data used for long term planning of ESRD health services;
- assist other agencies (GAO, CDC, NIH) in studies;
- provide feedback to Network facilities (accuracy check) on their population status. Quarterly and annual reports reflect activity and type of treatments.

QUALITY ASSURANCE AND SPECIAL INITIATIVES

The primary responsibility and function of the Networks is to ensure quality of care is maintained in the ESRD dialysis and transplant facilities within the geographic boundaries of their Network Council. The audits, Medical Care Evaluation Studies, Data analysis, facility site visits, and investigative studies that were conducted or initiated during 1981 demonstrates that a peer evaluation and monitoring process can be implemented. Highlights of this year's accomplishments are:

- completion of several morbidity and mortality studies;
- frequency of hospitalization studies;
- profile analysis by modality of treatment, facility utilization, demographic characteristics, primary disease, and survival;
- development of criteria for initiation of dialysis treatment;
- criteria sets and assessment methods for patient nutritional status;
- studies and the development of guidelines on the identification, prevention, management and surveillance of Hepatitis B and Non-A, Non-B Hepatitis.
- guidelines for water treatment safety;
- criteria established for adequacy of dialysis;
- studies on clinical management of renal osteodystrophy, anemia, potassium, blood pressure control, peritonitis in the peritoneal population, fistula access, and bacteremia and infection;

(continued on next page)

Quality Assurance and Special Incentives - continued

- joint investigations of sub-optimal care in ESRD facilities. Agencies that participation with the Network were PSROs, State Health Departments, and Medicare Regional Offices.
- Development of standarized forms for interfacility transfer of patient information, nursing kardex, long term patient care forms;
- study of the safety of dialysis equipment;
- guidelines for training new dialysis staff- role definitions;
- questionnaires on patient's knowledge and/or satisfaction with their treatment modality;
- CAPD studies on morbidity, mortality, and rehabilitation status;
- development of team site visits;
- study on reasons for nursing shortage in ESRD;
- time and travel distance study;
- evaluated protocol for pediatric services;
- study on salary range for nurses and technicians;
- arrangement of group rates for routine lab work to reduce the cost and waiting time for lab results;
- proposed revisions of local health codes which address ESRD facilities;
- development of uniform definitions for levels and types of care provided to acute and chronic patients to assist Medicare carriers in evaluating professional fee reimbursement to physicians.

REHABILITATION

In 1981, 50% of the 32 Networks identified the problems associated with rehabilitation to be of major importance for their Network to investigate. The variety of studies and educational efforts that have been completed or initiated are briefly illustrated below:

- One-fourth of the Networks have studies in process which are designed to identify factors in the patient population that does not permit return to employment. Some of these studies are also attempting to establish baseline levels of activity and/or employment status prior to the initiation of ESRD treatment.
- Conferences and workshops were conducted by Networks for ESRD staff on the promotion of rehabilitation.
- Joint meetings held with state rehabilitation agencies were held to explore and assist in clarifying the problems associated with encouraging rehabilitation.
- Establishment of Rehabilitation Task Forces to investigate barriers to rehabilitation.

PATIENT ACTIVITY

Consumer Advisory Groups have been established in two-thirds of the Networks. They serve as a source of support and information to ESRD patients. Among their various activities, these groups have:

- had input in developing literature for patient education including publications on patient rights, grievance procedures, nutritional handbooks, booklets on the various modes of treatment available;
- planned and implemented patient conferences for educational purposes;
- participated in Medical Review studies; and
- worked with other groups or agencies such as NAPHT, the Kidney Foundation, Renal Dietitians, and State Legislators;

EDUCATION

Networks have devised programs of education for their patient population, staff, and the general public. They have developed various means and approaches, including the following:

- Professional education:
    educational seminars and workshops (sometimes held in conjunction with state and local health agencies, on the following areas:
        dialysis, transplantation, hepatitis, nutrition, quality care, organ donation and retrieval, rehabilitation, medical records, form use, budget reduction, ethical issues, stress management, training for new staff.
- Patient education:
    - treatment modalities available
    - dietary workshops and nutritional booklets
    - patient information booklets
- Public education:
    - organ donor programs via brochures and posters
    - organized speaker bureaus for lectures
- Newsletters to patients and staff and health agencies
- Brochures and booklets developed concerning various areas:
    education and rehabilitation for patients, organ donation, staff training, patient information booklets.
- Telephone resource lines
- Resource libraries
- Lecturers made available

HEALTH PLANNING

All Networks prepare information for participation with local and regional agencies involved in ESRD health planning. Examples are:

- preparation of data for use in expansion/new ESRD applications;
- prepare review criteria for the need for ESRD services;
- produce incidence/prevalence data for long and short term planning (growth predictions and utilization patterns are determined);
- promote the efficient use of existing services;
- provide a major contribution to local agencies in determining need projections;
- provide data to facilities and potential providers of care for their planning activity; and
- participate in updating local state health codes to ensure quality delivery of care.

nachri **An Association Statement**

Statement of

The National Association of Children's Hospitals
and Related Institutions, Inc.

To the Subcommittee on Health of the
Committee on Finance

On the
Proposed Prospective Reimbursement Rates
for the End-Stage Renal Disease Program

March 15, 1982

The National Association of Children's Hospitals and Related Institutions, Inc.
Suite 34, Independence Mall, 1601 Concord Pike, Wilmington, DE 19803
Phone (302) 571-0882

Summary

- Pediatric ESRD programs have a higher cost per treatment than adult programs. This is due to their aggressive treatment philosophy and the high staffing level necessary to provide the intensity of services required by the complex patient-mix. The children's ESRD programs must rely on the exception process to recover reasonable costs for the services they provide.

- NACHRI is supportive of the change to a prospective reimbursement rate system for the End-Stage Renal Disease Program. The rate, however, must be based on articulated standards of care and operation and must not discriminate against any one group of patients or the providers of their care.

- The identification of the median cost of all dialysis facilities as the standard of efficient operation discriminates against hospital providers. The effect of this decision on Children's Hospital ESRD programs and the children they serve is potentially devastating.

- The exception process as developed in the proposed rule is inadequate. No indication as to the criteria which will be used by HCFA to judge the appropriateness of a request has been given. No limit on the maximum time by which HCFA must respond to an exception request is established. No indication is given as to what documentation a facility must present to receive an exception from HCFA.

- During the generation of the information necessary for approval of an exception request, providers will be underpaid for services rendered. Even if HCFA finds the higher program costs justifiable, a facility will be reimbursed for them only from the time HCFA accepts the request. No retroactive settlement is indicated in the proposed rule.

- This lack of clearly defined procedures for the exception request process undoubtedly will compromise the ability of HCFA to grant timely and appropriate exceptions to the proposed reimbursement rate. Such financial uncertainty may result in the reduction or elimination of Children's Hospital ESRD programs and place undue stress on the children and parents served by these programs.

The National Association of Children's Hospitals and Related Institutions, NACHRI, welcomes the opportunity to present to the Sub-Committee on Health of the Committee on Finance its views concerning the proposed changes to the End Stage Renal Disease Program. It is in the interest of children with end stage renal disease that the comments are submitted.

NACHRI is composed of 73 Children's Hospitals, both free-standing and university hospital affiliated. Included among these institutions are the vast majority of the major teaching Children's Hospitals. Member hospitals admit over 90 percent of the patients cared for in Children's Hospitals and provide in excess of 2.3 million days of inpatient care per year. Additionally, they experience nearly 4 million outpatient visits a year, and conduct extensive educational and research programs. Annual expenditures on behalf of their patients exceed $1.2 billion.

The Association is organized in the recognition of the importance of child health care, providing a forum of hospitals which specialize in the care of children. Its main purpose is to promote the quality of child health care through the dissemination of information and the promotion of research and education programs related to that care.

In the performance of its mission, NACHRI has willingly accepted the role of advocate for the child. When policies, regulations, or legislative proposals germane to providers of health care reflect a particular impact on the needs of children NACHRI addresses them, pointing out their effect on child health care. In exercising this advocacy role for children, the Children's Hospitals speak to the rationale for their very existence. The acknowledgement that the child is different; different in his metabolism, in his reaction to the disease process, in his emotional and social needs, and in the methods of care needed to maintain or restore his normal health status provides the impetus for institutions dedicated solely to the care of children. This recognition of the unique characteristics and needs of the child population, specifically pediatric end stage renal disease patients, coupled with the child population's limited ability to speak to its own needs motivates the development and submission of this statement.

NACHRI AS A SOURCE OF DATA

In recognition of children's highly unique needs, NACHRI has been collecting utilization, cost and patient characteristic data from the Children's Hospital programs in an effort to establish an information base on the pediatric portion of the ESRD population. Many of the findings of these ongoing studies will be cited in this statement.

OVERVIEW OF PEDIATRIC ESRD PROGRAMS

End stage renal disease has a very low incidence in the child population. According to HCFA data only 5.17% of the Medicare ESRD population in 1980 was under the age of twenty; approximately 2,870 children, a decline from the 3,100 children reported enrolled in the Medicare ESRD program in 1979.

There are approximately 46 hospital-based ESRD programs with specialized capabilities for treating children. Thirty of these programs are located in university based hospitals or hospitals with a major teaching affiliation, and as a consequence, the majority do not segregate incidences of children's treatment. The costs of treatment provided to children generally are merged with the costs of other, adult patients.

It is in the Children's Hospitals' programs that the special needs of children and the full impact of their care can be measured. At the end of 1981, there were 16 Children's Hospitals providing dialysis care to children with end stage renal disease. Ten of these hospitals were also certified as transplant centers. Data available from 12 of these programs show that in 1980 they provided care for nearly 13% of the HCFA reported pediatric ESRD population.[1] In addition to the vital role of providing essential services to the children from their immediate environs, these 16 Children's Hospitals also serve as regional referral consultation and teaching resources in the care of all children with end stage renal disease. They are the site of research on the cause, prevention and treatment of end stage renal disease, and on maximization of growth and development in children with this disease.

PEDIATRIC TREATMENT GOALS

The stated goal of pediatric ESRD treatment is restoration of normal renal function through transplant, so that the growth and development process is compromised as little as possible and the child may develop to a healthy, productive adult. During the course of treatment prior to transplant, emphasis is placed on maintaining a normal life for the child to the extent possible. The activities of a "typical" child revolve around school and home. NACHRI's study shows that a high level of school attendance has been maintained for these children. A survey which gathered information on 117 pediatric ESRD patients found that nearly 78% of the school age children attended school on at least a part time basis.

There is also a motivation towards home dialysis for pediatric patients whenever appropriate. Of the patients being treated in 13 of the Children's Hospital programs at the end of 1981, over 35% were on home dialysis, compared to HCFA's reported overall home dialysis rate of 17%. Seventy percent of the children on home dialysis were treated by the CAPD modality.[2] The percentage of patients on home dialysis in 1981 represents a 37% increase over the percentage receiving this treatment modality at the end of 1980.

EVALUATION OF HCFA PROPOSAL

Among providers and recipients of ESRD services, much concern has been expressed over the inadequacy of both the cost and patient data used to construct the proposed rule published by HCFA.

HCFA relied on the cost data from a limited number of hospitals and freestanding dialysis facilities in developing its proposed reimbursement rate. Although the Bureau of Health Insurance and its successor HCFA have been responsible for the ESRD program since the early 70's, no standards for an efficiently and effectively run program have been promulgated. As a consequence, the median cost of the hospitals and freestanding units combined has become the standard for cost-effective delivery of services. And although hospital units experienced higher costs in three component areas; labor, supplies, and overhead, only the excess overhead costs resulting from Medicare cost finding regulations and medical education were deemed justifiable higher costs. For costs which appear atypical from

HCFA's limited data base, the provider must seek a prospective exception, within 180 days of notification of its reimbursement rate.

The proposed rule acknowledges that atypical patient mix may justify an exception to the reimbursement rate. The burden of proof rests with the provider, to demonstrate that its costs generate from this or other factors beyond its control, without benefit of elaboration by HCFA of these factors. If approved for an exception the new rate will be granted retroactively to when HCFA accepts the request for exception rather than when it was filed. Since the proposed rule does not designate a time frame for when action must be taken by HCFA once an exception request is filed, a facility may well be underpaid for its services for an extended period.

This Association senses that HCFA intends to develop such a body of knowledge on ESRD program costs and patient mix through its exception request review process, rather than through independent analysis. Since during the generation of this knowledge, providers of care may be placed in financial jeopardy and their ability to serve patients compromised, we regard this approach as putting undue and unnecessary stress on beneficiaries and institutions. Further, given the demonstrated slowness with which HCFA has considered similar exception requests, the provider of services may supply a considerable volume of services without knowing if or when full payment for their cost will be made.

THE PROPOSAL AND THE NEEDS OF CHILDREN

The decision to utilize the median cost for all facilities as the cost standard has a potentially devastating effect on the Children's Hospital ESRD programs. General attributes of the child coupled with the characteristics of end stage renal disease in children have resulted in a treatment philosophy that is in the interest of the child, and consequently in the interest of society as a whole. These programs emphasize a cure-oriented course of treatment, culminating in early transplant. This results in higher short term costs for care of children with ESRD. The long term costs to society however are lower since the costs of continuing maintenance dialysis as these children mature to adulthood are eliminated.

Data which have been collected from the Children's Hospital programs document the atypical nature of both the child ESRD patient and the pediatric ESRD program. Unlike adult programs where maintenance of life is the primary treatment goal, children's programs employ an aggressive treatment regimen and emphasize early transplantation. A survey of 117 children receiving care in Children's Hospitals' programs during September 1981, indicated that the average time between initiation of dialysis services for these patients and transplantation was 6.76 months. Forty-seven percent of the 117 patients had undergone 1 or more transplants. Of the remaining children, 61.3% were currently awaiting a transplant. This high incidence of transplantation is confirmed by a similar study of 115 pediatric patients conducted by Network 11 in Texas.[3] It found that 95% of the patients under 16 had either received a transplant or were current candidates for one. This is in marked contrast to adult programs where the emphasis of treatment is maintenance, with a resultant transplant rate of 9% as reported by HCFA. Complete results of NACHRI's survey are provided in Appendix A.

The limited incidence of ESRD in children, the need for a catchment area of reasonable size, and the high transplant rates result in pediatric programs having smaller patient loads. The patient load for 14 Children's Hospital programs during the 7/1/81 to 12/31/81 reporting period was 13.3. The services rendered to these children, however, are intensive and result in a high staff to patient ratio for the children's program. These are several of the reasons for the cost per treatment in pediatric programs being generally higher than the cost per treatment in both freestanding facilities and general hospital units.

The Children's Hospital programs also demonstrate a high rate of turnover in the treatment of children. During three six months reporting periods, 7/80 to 12/80, 1/81 to 6/81, and 7/81 to 12/81, the turnover ratio was .49, .57, and .49 respectively. This turnover rate of approximately 50% (patient losses from the programs are generally equal to additions for any given reporting period) results in continuing evaluation, orientation, and education of newly diagnosed ESRD patients, and preparation of children and parents for transplantation. These are major elements of the pediatric programs and are also factors which add considerably to their costs.

Labor costs are a significant factor for Children's Hospital programs. The unique characteristics of the pediatric population often require more individualized and intensive therapy, resulting in patient to staff ratios of 3:1, and even 2:1, being not uncommon in pediatric programs.[4] The small body size of the child ESRD patient requires close monitoring when dialyzing. Maintaining the proper fluid balance and medication level is critical and the limited blood volume of a child greatly reduces the margin of allowable variance before serious complications can occur. The size and weight of the child may change quite frequently requiring additional lab work to assure the proper dialysis routine is carried out each time. Furthermore, staff must not only attend to the needs of the child, but also must be available for explanation and support to the parents during the course of treatment.

The intensive treatment required for children is also a result of the disease characteristics in the child. To illustrate this fact, a comparison with data cited by Lowrie and Hampers to support their view that freestandings and hospitals treat clinically similar patients is provided.[5] They summarize the five most common diagnoses for a sample of patients on dialysis in 1980. (Since the mean age of this sample was 53.5, it is assumed to have been a predominantly adult population.) Similarly, disease characteristics were collected in the NACHRI study of children's programs. Glomerulonephritis was the most common primary diagnosis indicated for nearly 30% of the children, as it was most common for the adult sample. It is with this measure however, that the similarities between the two age groups end. The next two most frequent diagnoses for children were congenital obstructive uropathy and renal dysplasia, presenting great clinical challenge. The adult sample exhibited hypertension and diabetes as the next most common diagnoses, not evident as a primary diagnosis among the children studied.

Unlike the Lowrie and Hampers study, NACHRI's study does report on complicating conditions. A mean of 4.81 complicating conditions per child is demonstrated. One of the more frequently cited complicating conditions. potential growth retardation, was indicated for nearly 71% of the sample. This is a particularly severe problem prevelant throughout the child ESRD population, and over 53% of children in the study were reported to have an identified poor growth potential. Since adults perforce have achieved full growth, problems in growth and development are not a common complicating condition in the adult population.

Thus, it can be seen that the manifestations of end stage renal disease differ between the child and adult populations. The overwhelming probability of the presence of complicating conditions in the pediatric patient indicates that an increase in the level of services provided to virtually all of these patients is to be expected. This in turn also necessitates a higher staff level to treat the resulting atypical and complex case-mix.

THE PROPOSAL'S TREATMENT OF SUPPLY COSTS

HCFA anticipates that hospitals should be able to exercise the same economies in purchasing and reuse of supplies as for the typical patients of the large freestanding facilities. Higher costs for supplies therefore, were not recognized in the development of the reimbursement rate. The bulk preparation of dialysate is not appropriate for children. Factors such as blood volume, body size, and complicating conditions that vary from child to child prohibit this practice since a greater degree of individual dialyses prescriptions are required. The children's programs' smaller patient volume may mitigate against bulk purchasing of supplies. The supply inventory must contain a variety of sizes for items such as dialyzers however, to accommodate the needs of the children. The purchase of supplies therefore is specialized and costly.

HISTORICAL COSTS OF CHILDREN'S PROGRAMS[6]

Study of utilization and cost data for 13 Children's Hospital ESRD programs for their fiscal years ending in 1980 shows that on average, these programs provided 890 hemodialysis treatment sessions. They also provided a total of 7,500 additional outpatient hemodialysis sessions that were not covered by Medicare. The average cost per session was $276, an 8% increase over their cost per hemodialysis treatment in FY 1979. The total cost of hemodialysis treatments provided by these 13 hospitals to Medicare patients in FY 1980 was $3.2 million, a small percentage of the total ESRD program costs. Of this total Medicare cost however, slightly more than one-third was above the payment screen in effect. Projecting a payment rate of $132 per dialysis treatment would result in over 50% of the Medicare costs for the Children's Hospitals programs being over the limit.

THE PROPOSAL'S EFFECT ON CHILDREN AND THEIR PROVIDERS

HCFA has recognized the higher costs of children's programs in the past and 8 of the 13 hospitals had been approved for an exception to the then target rate of $138. The exceptions granted however, often were not adequate to cover the full costs of the program. If future exceptions do not recognize the full cost of the services, these children's programs will be in definite jeopardy. The Children's Hospitals and more importantly the children they serve have been disproportionately affected by the reductions that are occurring in health and social services. Children's Hospitals which in 1980 experienced over 67,000 Medicaid admissions and 622,000 Medicaid days representing 30% of their total inpatient days,[7] are being severely impacted by cuts in state Medicaid programs. An ESRD program which has not recovered its cost in the past and may require a greater future subsidy while benefiting a relatively small number of patients, is not in an enviable position in the hospital which may be faced with reducing services and programs because of less than adequate reimbursement for great numbers of other patients.

The reduction or elimination of ESRD programs serving children would be of great significance to the pediatric patients and parents served by these programs. At best it would require an adjustment to a different dialysis program with a different philosophy of treatment, not geared to the needs of the child. At worst, it might preclude access to adequate services.

The proposed reimbursement rate has the potential of penalizing children's programs for their emphasis on the special needs of children and transplantation, both factors in the higher costs of these programs. Further, by having developed home dialysis to more than double the national rate, these providers may be adversely impacted by the proposed rate's effort to stimulate this choice of treatment site. In the event that the Children's Hospital programs are not granted exceptions from the proposed reimbursement rate quickly and expeditiously, they may be forced to reduce or eliminate the service. The children will have to turn to the lower cost maintenance programs for care. If treated according to a program philosophy of maintenance-oriented care as opposed to cure-oriented care through transplantation, they will continue to generate program costs for years to come.

CONCLUSIONS

NACHRI agrees that the rising costs of the ESRD program necessitates its cost effectiveness, although we recognize that these rising costs are a function more of increased patient loads than of inefficiencies of operation. We are also supportive of the proposal for a change to a prospective reimbursement rate system. However, this system must be based on agreed upon standards of care and operation, and must not discriminate against any one group of patients or the providers of their care.

We are encouraged that pediatric units are cited examples of programs with atypical patient mix at several points in the proposed rule. We do not espouse a separate pediatric rate for ESRD services, since costs differ even among the Children's Hospitals, in varying stages of development of their ESRD programs. It is our position that the exception process must recognize that newer programs often experience the higher costs associated with start up and initial low utilization, and the criteria upon which exception requests are judged for appropriateness must be codified and known. Without these identified standards, providers seeking exceptions to the reimbursement rate will be engaged in a guessing game of serious financial proportions, and HCFA faces the difficult challenge of avoiding arbitrary decision making.

To this end, the Association has under consideration development of a uniform system of costing, budgeting, and exception request preparation for use by Children's ESRD programs. It is our intention to invite HCFA's participation in the development of this system.

Alan B Gruskin, MD

Alan Gruskin, M.D.
Chairman
ESRD Council

Robert H. Sweeney
President
NACHRI

REFERENCES

1 Children's Hospitals' 1980 Facility Surveys (Form HCFA 2744).

2 Children's Hospitals' 1981 Facility Surveys (Form HCFA 2744).

3 Hogg RJ, Murphy J, Conley S. Lynch R. A Regional Network Review of Health Care Delivery to Children and Adolescents with End-Stage Renal Disease. ESRD Network 11 Medical Care Evaluation Study for 1980-1981, p. 3.

4 Ibid., p. 1.

5 Lowrie EG, Hampers CL. The Success of Medicare's End-Stage Renal-Disease Program. The Case for Profits and the Private Marketplace. N Engl J Med. 8/20/81 434-438. p. 436.

6 Children's Hospitals' Medicare Cost Reports (Form 2552), Supplemental Worksheet E-3.

7 Children's Hospitals 1980 AHA Annual Survey of Hospitals.

Appendix A

RESULTS OF THE PEDIATRIC ESRD PATIENT PROFILE

To test the appropriateness of the development of a profile of children with end stage renal disease, six children's hospitals with ESRD programs were asked to complete a patient questionnaire for each patient currently receiving maintenance dialysis services. The patient questionnaire was developed with the guidance of Alan Gruskin, M.D., and Paul McEnery, M.D., members of NACHRI's ESRD Council. This process provided a sample of 117 current pediatric ESRD patients.

PATIENT CHARACTERISTICS

Following are statistics displaying the demographic and socioeconomic characteristics of the patients in the sample.

- Sex

Male	58.97%
Female	41.03%

- Race

White	67.52%
Black	18.80%
Hispanic	11.11%
Other	2.56%

- Age

Mean = 13 years 8 months
Median = 14 years 1 month
Range = 1 year 6 months - 25 years 6 months

- Family Composition

*% of Patients living with:		Avg. # of Siblings at home:
Both parents	62.39%	1.86
Mother	23.93%	1.67
Father	4.27%	1.60
Other	9.40%	1.90

- Family Income[1]

Less than $20,000/yr.	67.37%
More than $20,000/yr.	32.63%

- Patient School/Employment Status

Preschool age	7.69%
Attends school full-time	33.33%
Attends school part-time	35.04%
Tutor	3.42%
Unable to attend school	7.69%
Works part-time	4.27%
Unable to work	8.55%

- Patient School Performance (for 84 patients attending school)

Full-time above average	9.52%
Full-time average	28.57%
Full-time below average	8.33%
Part-time above average	1.19%
Part-time average	19.05%
Part-time below average	28.57%
Tutor average	2.38%
Tutor below average	2.38%

- Presence of Behavior Problems

Behavior problems present	40.52%
No behavior problems present	59.48%

DISEASE CHARACTERISTICS

Following are statistics illustrating disease characteristics of the patients in the sample.

ESRD Primary Diagnosis		% of patients
Glomerulonephritis		29.91%
chronic undifferentiated	1.71	
MPGN	5.98	
FSGN	5.98	
RPGN	5.13	
Other	4.27	
Unspecified	6.84	

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[1] 49.1% of all families in the U.S. had an income level of $20,000 or more in 1979. U.S. Department of Commerce, Statistical Abstract of the United States, 1980, p. 450.

- ESRD Primary Diagnosis

ESRD Primary Diagnosis	% of patients
Obstructive uropathy, congenital	18.80
Renal dysplasia	11.11
Hypoplastic kidneys	5.98
Cystinosis	5.13
FGS	5.13
Other interstitial nephritis	4.27
Polycystic kidney disease	2.56
Wilms Tumor	2.56
Medullary cystic disease	2.56
Reflux nephropathy	1.71
Sickle cell anemia	1.71
Lupus	1.71
Other	6.84

- Presence of Complicating Conditions

Complicating Condition	% of patients
Renal osteodystrophy	83.76
Growth retardation	70.94
Neuropathy, peripheral	35.90
Seizure disorder	54.70
Psychomotor retardation	37.61
Cardiac manifestations	52.14
Cardiovascular	38.46
Hypertension	45.30
Nutrition	21.37
Anemia	5.13
Hypotension	2.56
Respiratory	1.71
Other	14.53
None	3.42

543 complicating conditions are currently present in 113 patients. The mean number of complicating conditions presented is 4.81.

- Ability to Walk

Good	52.14%
Fair	29.06%
Poor	17.95%
Unable	0.85%

- Growth Potential

Good	21.37%
Fair	25.64%
Poor	52.99%

TREATMENT CHARACTERISTICS

The following statistics demonstrate characteristics of treatment of children with end stage renal disease.

- Current Dialysis Treatment Modality & Setting(1)

  - Hospital Unit - 76.07% (89 patients)

Hemodialysis	76 patients (85.39%)
IPD	13 patients (14.61%)

  - Home - 23.93% (28 patients)

CAPD	19 patients (67.86%)
IPD	8 patients (28.57%)
Hemodialysis	1 patient (3.57%)

  - Duration of Current Dialysis Regime

Mean = 20.43 months
Range = 1 month - 96 months
47.41% of the patients have been on current dialysis regime for 12 months or less.

  - Months from Recognition of Progressive Renal Failure to Initiation of ESRD Services

Mean -	43.83 months
Median -	16.50 months
Range -	0 months - 271 months

Medications Prescribed

  - Total Medications Prescribed

Mean -	6.18
Median -	6.00
Range -	2.00 - 12.00

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[1] At the end of 1979, home dialysis patients represented 13.04% of the total dialysis population of which 94.3% were 19 years of age or greater. Programs End-Stage Renal Disease Second Annual Report to Congress, FY 1980, p. 1.

- Antihypertensive Medications Prescribed

Prescribed to 45.30% of patients

Mean -	1.72
Median -	2.00
Range -	1.00 - 4.00

- Transplant Experience (55 patients)

47.01% of the patients in the sample have received 1 or more transplants. The average number of transplants per patient transplanted is 1.51. 85.54% of the transplanted kidneys were cadaveric, and 14.46% were from living related donors.

- Survival of the Graft

Cadaveric (mean)	10.63 months
LRD (mean)	9.58 months
Total (mean)	10.52 months

- Average Time between Initiation of ESRD Service and First Transplant

Mean = 6.76 months

81.82% of the patients who have received transplants received their first transplant within 12 months of initiation of ESRD services.

- Patients Never Transplanted (62 patients)

52.99% of the patients in the sample have never received a transplant. 61.29% of these patients are currently awaiting transplant. 38.71% are not currently candidates for transplant.

- Average Time between Initiation of ESRD Service and Entry on Transplant Registry or Commencement of Preparations for LRD Transplant

For those patients who have never received a transplant and who are currently awaiting a transplant, the mean time between initiation of ESRD service and entry on transplant registry or commencement of preparations for a LRD transplant was 6.97 months.

87.10% of these patients were entered on a registry or preparations were started for a LRD transplant within 1 year of initiation of ESRD service.

41 patients, 35.04% of the sample population are not currently candidates for transplant.

FINANCIAL INFORMATION

- Medicare Status

Medicare covered	70.94%
Medicare applicant	23.08%
N/A	5.98%

- Payment of Coinsurance and Deductible

Medicaid only	18.80
Title V only	3.42
Private or group insurance only	41.88
Medicaid & Title V	17.09
Title V and private insurance	3.42
Medicaid & private insurance	2.56
Medicaid, Title V, & private insurance	3.42
N/A	9.40

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12/81

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March 25, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lighthizer:

We are writing you this letter regarding the Senate hearing on the proposed prospective reimbursement rates for the end stage renal disease program held March 15, 1982. The following represents our comments on the HCFA regulations as published in the Federal Register of February 12, 1982.

Although we can agree and appreciate the general intent of the regulations, we feel that, as written, these regulations are excessively punitive to hospital-based facilities which serve as the back-up tertiary care centers to the limited care facilities.

If these regulations are adopted in their current form, we also worry that the resultant constriction of the number of such back-up centers will result in abuses in the use of inpatient dialysis with its accompanying costs. The following discussions point out the major issues as well as dealing with the methodology, adjustments and other detail included in the regulations.

I. Major Issues:

A) Three Kinds of Facilities:

We would like to point out that there are three kinds of institutions rendering care to outpatient hemodialysis:

1) Non-hospital limited care facilities which tend to treat chronic, stable outpatients.

2) Hospital-based limited care facilities, who also treat chronic, stable outpatients and

3) Hospital-based tertiary back-up centers which treat the unstable, acutely ill outpatients. We feel that the regulations do not take into account this third type of tertiary care provider and by ignoring the existence of same have developed regulations which are

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excessively punitive to those institutions which do provide that kind of necessary care. We further believe that tertiary back-up centers are absolutely required in order to have an effective renal disease treatment network, and that such facilities have higher labor and indiract cost due to their unique nature and the types of patients which they see.

Nevertheless, HCFA has stated that, "Some hospital units claim that one reason they have higher labor costs is that they treat more patients with multiple conditions or other complications..... We have examined age, sex, race, and utilization rate (discharges and days of care).... We conclude, therefore, that with respect to these measures of patient need, there is no great difference between hospital-based and independent facilities.... (Therefore) We propose to allow no specific adjustment for labor costs." As a tertiary care back-up hospital facility, we disagree with this assessment and argue that hospitals should be broken down into two categories:

1) Hospitals which serve as a limited care facility rendering primarily chronic outpatient dialysis and

2) those hospitals which serve as a back-up tertiary care type of facility who tend to treat the sicker and more unstable patients.

Hospitals in the latter category tend to be institutions associated with a major transplant center and oftentimes have little to do with the rendering of the typical routine chronic outpatient dialysis. These back-up dialysis units do treat patients who are sicker and require more intensive labor per treatment. As an example of the kinds of patients which would be treated in a back-up unit as opposed to a limited care setting, you would have:

1) Patients who have been recently diagnosed as end stage renal disease patients and who have not yet been stabilized.

2) Patients who have access problems in regard to their fistula or graph.

3) Patients who tend to be recent postoperative patients, who are still unstable and tend to be too sick to be seen in a limited care unit.

4) On a rare occasion you would have patients with a history of chest pain while dialyzing which tend to be too sick and too great a risk to be dialyzed in a limited care facility,

5) Paraplegics and bilateral amputees who generally require more acute back-up and one-on-one nursing care as well as special equipment because of the nature of their debilitation.

6) Severe psychiatric or drug problem patients who tend to be unstable, disruptive and unable to care for themselves and, therefore, unable to help with their dialysis; patients who are blind or who have suffered from nerve damage as a result of, for example, diabetes; or patients who cannot hold a needle site because of illness, etc. tend to be treated in an acute facility.

In general, patients who are treated in the back-up facility tend to be unstable and very sick patients. As a consequence, these back-up facilities are unable to recognize the economies of scale which are realized in terms of staffing in a limited care facility which treats only stable, dialysis patients. Back-up facilities require a higher staffing level; and, therefore, are more labor intensive than your independent facilities. Any regulations which are proposed by HCFA should recognize this fact.

If care is not available to such acutely ill patients through the tertiary back-up outpatient units, it is highly probable that these patients will receive the necessary care as an inpatient, which costs significantly more than outpatient dialysis.

B) The cost-finding Formula required by Medicare should be reevaluated for hospitals providing out patient dialysis. The excessive overhead which is required to be allocated to outpatient dialysis is not being adequately considered in the regulations. Specifically, the regulations have included a $2.10 per dialysis adjustment to compensate hospitals for excessive overhead. However, in fiscal 1981 the University of Cincinnati Hospital - General Division was required to include $154.42 per dialysis for overhead alone. Approximately 59% of our total dialysis costs can be attributed to overhead or indirect cost because we are required to follow the Medicare cost-finding formula.

It is our opinion that because of the higher cost nature of such back-up facilities and the necessity to maintain such units, HCFA should reevaluate the manner in which these facilities are reimbursed. Specifically, we feel that HCFA should not include these back-up facilities in the same category as the hospital-based limited care providers who render care primarily to stable, chronic outpatients.

If the regulations fail to recognize this difference, we fear that many such back-up units will discontinue providing this service on an out-patient basis.

II. METHODOLOGY

A) Sample Selection: The regulations do not indicate that the 110 facilities selected were selected at random.

Additionally, the regulations do not indicate by what method the samples were chosen from each stratum. In fact, it appears from the regulations that the samples selected may have been further stratified by cost. An example was given which stated, "from this array we selected facilities from each stratum (e.g. urban independent facilities with reported annual costs of $500,000 or less) according to a statistical optimum allocation technique." The question then remains whether there was further stratification of the sample selection by cost and whether a predominate number of facilities with low cost were consequently selected to be part of the sample size. In short, we would like HFCA to present what portion of the sample represented high cost tertiary care back-up centers.

B) Sample Stratification: The regulations indicate that the sample was selected using a stratification based on the four-celled approach, (i.e. urban independent facilities, urban hospital-based facilities, rural independent facilities, rural hospital-based facilities). Ultimately this stratification was not appropriate because the regulations only stratified provider facilities into two groups, the hospital-based and the independent facilities. Consequently, it is possible that the sample selection are biased in favor of low cost facilities.

C) Use of the Median: Per the proposed methodology, the use of the median is a better measure of the central tendency of data. Unfortunately, that does not necessarily imply that it would provide a better means of measuring an equitable cost reimbursement. It is possible to use a concept of mid-range which by definition includes only a certain proportion of the values in the middle of a value set when it is felt that a few extreme values of a data set will inordinately skew the reliability of the mean. Using a mid-range would exclude values at both the upper and lower ends of the data set and would enable the mean to be a more appropriate measure of average cost. It is apparent that if a distribution is skewed to the right of the mode then this positively skewed distribution would have a mean that would tend to be greater than the median. If, in fact, the sample selected by HCFA was positively skewed, then perhaps a more appropriate measure of average costs would be the mean rather than the median.

D) Use of the Median Cost for All Facilities: The use of median cost for all facilities as the basis for the reimbursement to both independent facilities and hospitals seems to be excessively punitive to the hospitals. The median rates stated in the proposal, (i.e. that the median cost of all facilities was $125.53 and the median cost of hospital-based facilities was $135.11) indicates that hospitals without the 5% adjustment would be reimbursed at 93% of their median cost in years 1977, 1978 and 1979. Even after adjusting this rate by the 5% figure, this as-adjusted rate of $131.81 still represents only 97 1/2% of the median cost of hospital-based facilities during the years 1977, 1978 and 1979. It stands to reason that given current figures from the most recent cost reporting year that this as-adjusted median cost for all facilities will represent far less than the 97 1/2% of hospital costs.

E) Adjustments in Setting the Rate (p. 6565)

1. 5% Adjustment: The use of the 5% adjustment to developing the hospital-based rate is arbitary. The regulations state that in developing the hospital-based information the median cost for all facilities should be adjusted by a 5% figure in order to take into account the increased costs of hospital-based programs. The 5% figure does not appear to be based on any documented evidence but rather appears to be an arbitrary figure selected by HCFA to compensate hospitals for costs which are higher than that which is recognized under a median cost formula for all facilities. We would like to suggest that, by recommending a 5% adjustment, HCFA has implied that the formula as stated is inequitable and is overly punitive to a hospital-based facility. We would further like to suggest that appropriate cost-finding and cost accounting techniques should be employed which would make any adjustments in the computation of hospital-based rates more realistic and based on true costs.

2. $2.10 Excess Overhead Adjustment: The use of the $2.10 per treatment adjustment to equalize overhead costs between hospitals and free-standing facilities seems to be inordinately low. In a large tertiary back-up center we find that our indirect expenses equal approximately 150% of our direct costs because of the cost-finding formula which is required by Medicare. We would like to suggest

that HCFA use a more equitable adjustment to equalize for this overhead.

F) Computation of Home Care Composite Rates: We feel that $97 average cost for home care facilities is incorrectly computed. We based this statement upon a simple algebraic calculation and upon current knowledge of the percent of patients who receive home hemodialysis versus home CAPD and home IPD treatments. In short, although home IPD is a home treatment modality, it is rarely used and represents such an insignificant amount that its percentage of use approximates 0%. This means that the home treatment for renal patients is comprised of primarily home hemodialysis and home CAPD. If one accepts the above, then the percentage of use estimated by HCFA for each treatment modality although not given could be derived as follows:

$$\left(\begin{array}{l}\text{\% of patients}\\ \text{receiving home}\\ \text{hemodialysis}\end{array}\right)\left(\begin{array}{l}\text{Cost of home}\\ \text{hemodialysis}\end{array}\right)+\left(\begin{array}{l}\text{\% of CAPD}\\ \text{patients}\end{array}\right)\left(\begin{array}{l}\text{Cost of}\\ \text{CAPD}\end{array}\right)=\begin{array}{l}\text{Weighted}\\ \text{Average}\\ \text{Cost of}\\ \text{Home}\\ \text{Dialysis}\end{array}$$

$$(X)\ (\$87) + (1-X)\ (\$114) = \$97$$

By computing this formula, one could determine that X = 63% which represents the percentage of patients receiving home hemodialysis. 1 - X = 37% represents the number of patients receiving home CAPD treatments. From actual practice which we have observed at our neighboring facility at DCI, Cincinnati, the operational figure currently is about four patients on home hemodialysis and 20 patients on CAPD. At the Veterans Administration Hospital in Cincinnati the figure is about four patients on home hemodialysis and 32 patients on CAPD. It seems appropriate then, that if Cincinnati's experience is representative, and we believe it is, the present proportion of patients on home hemodialysis should be somewhere between 10 and 20%, (not 63%) and the proportion of those patients on home CAPD should be between 80 and 90% as opposed to the 37% used by HCFA. If, Cincinnati's experience is representative then the weighted average median costs for home hemodialysis should be, in fact, somewhere between $111.30 and $108.60 rather than the $97 as indicated on page 6563. This could be computed as follows:

$$(10\%)\ (\$87) + (90\%)\ (\$114) = \$111.30$$

Or alternately,

(20%) ($87) + (80%) ($114) = $108.60

Either way, the median cost computed represents a far greater median cost than the $97 indicated. Consequently, it is our opinion that the percentages used in the HCFA computation is not representative of actual practice and needs to be adjusted accordingly.

G) Use of General Wage Index to Equalize Labor Costs: We have examined the wage index suggested and have compared it to a small informal survey which we conducted of our professional staff who make up the majority of our staff in renal dialysis. In the case of New York and California, we have found the salaries of both head nurses and staff nurses to be far more comparable to Cincinnati's than the index would suggest. Consequently, we feel that HCFA should reanalyze the index used and we would like to suggest that HCFA base their index upon professional staff wages and not on a general wage index.

III. Questions:

1. What accounted for the 25% total adjustment made to the hospital's costs which were attributed to supplies? (Page 6563).

2. Is the limit of $32,000 per year which was applied the compensation of administrators and medical directors of independent facilities reasonable and realistic given the current salary structure for these individuals? (Page 6563).

3. Upon what basis was the statement made that, "We believe our cost review results reasonably represent the median cost of furnishing home dialysis"? In the succeeding paragraph, HCFA indicated that "Due to severe time constraints it was impossible to actually determine if all costs were reasonable and allowable under Medicare principles of reimbursement or to establish rigorous comparable cost centers in any detail." (Page 6563).

4. Regarding the development of the cost for home dialysis, were the 23 dialysis facilities and two state kidney programs selected at random or was the selection of these facilities based upon their low cost nature? (Page 6563).

5. Why was HCFA unable to spend the time determining if the cost of these 25 home dialysis programs were reasonable and allowable under Medicare? HCFA did exactly this for the sample of 110 non-home care facilities.

IV. Comments:

A) HCFA has stated that they believe the payment for a treatment session is the most obvious unit of reimbursement. Although we agree it is the most obvious unit of reimbursement, we question whether it is in fact the most equitable method of reimbursement. It appears that this method of reimbursement does not take into account the level of care which is rendered and which should be based more upon the acuity of the patients than on the fact that they received dialysis.

B. HCFA has concluded that "no specific adjustment is appropriate to account for any inflation costs that may have occurred since our audits were conducted of reports for fiscal years ending 1977, 1978 and 1979...." In general, the evidence indicates that the provision of dialysis services has been characterized by increased efficiencies. This conclusion was based on the observation of the number of dialysis facilities which has increased from 606 in 1973 to 1,120 as of October 1, 1981. HCFA concludes, therefore, that efficiently operated facilities are not incurring suddenly rising costs. We do not agree with this conclusion and would question whether the increase in 514 facilities were primarily in the category of limited care facilities which dialyze primarily chronic, stable outpatients. It is our contention that the back-up tertiary care facilities have not been able to operate within the $138 screen which was established in 1973. We would further like to request that HCFA provide the number of facilities which are currently operating under an exception to the 1973 rate, and we feel once they have provided this information, we will be able to deduce more conclusively whether their conclusion that efficiently operated facilities are not incurring suddenly rising costs is correct, or whether that statement applies merely to those limited care facilities who are treating stable, chronic outpatients and who have been able to defer more complicated cases to the back-up units.

IV. Summary

In summary, we have projected the impact of the proposed regulations on last year's outpatient renal unit. If the Regulations had been in effect during our last fiscal year, we would have lost approximately $164,509. Future losses under this program are expected to exceed this amount. In light of this, should the proposed regulations be adopted, it is highly probable that our outpatient dialysis program will be discontinued.

We appreciate the opportunity to make known our position on the proposed regulations. We would be happy to discuss our concerns with you if necessary.

Again, thank you for your consideration.

Sincerely,

Vito F. Rallo

Vito F. Rallo
Administrator
Cincinnati General Division

VFR/km

W88-88.4

Beth Israel Hospital

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March 22, 1982

Robert Lighthizer, Esq.
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington D.C. 20510

RE: March 15 Hearing on Proposed Reimbursement Rates for End-Stage Renal Disease

Dear Mr. Lighthizer:

I am writing in follow-up to the March 15 hearing of the Subcommittee on Health which reviewed the proposed prospective reimbursement rates for end stage renal disease (ESRD). It is my intent to present data which will show that hospitals like the Beth Israel provide ambulatory dialysis to a patient population which cannot be handled by the independent facilities, and to show that these patients are not appropriate candidates for home treatment, thereby justifying the higher costs of some hospital based units which are explained by higher staffing ratios and burdensome overhead allocations.

It should first be pointed out that there are two different types of hospital based facilities. The first treats ESRD patients on a non-selective regional basis. These units are somewhat similar to the independent facilities in the types of patients in their case mix. The second (Beth Israel being an example) refers out all stable ESRD patients to the lower cost independent facilities for treatment or home training and retains only those patients whose medical conditions warrant hospital based dialysis. We feel that if units like ours are to survive, and there is a large population of patients whose continued existence depends on units like ours, that this critical difference in patient populations must be specifically recognized by the regulations. We request that the regulations specify that hospital based units which can document that they refer all stable ESRD patients out to independent facilities and retain only unstable patients will be granted an exception to the rate screen.

It is the present position of HCFA that there is no major difference between the ESRD patient being cared for by hospitals like Beth Israel and those being cared for by the independent facilities. The Health Care Financing Administration points out that the medical conditions and complications are similar for both sites. What this position fails to take into account, however, is the status of the patient and the patient's functional capacity. Within every medical diagnosis code there is a group of patients which is stable and a group which is seriously ill. Using Beth Israel's current ESRD patients as an example will illustrate this point.

1) Our patients are considerably older. As of March 1, 1982 the median age of the 31 patients in our hospital based dialysis unit was 69, compared to a median age of 61 for the 81 Beth Israel patients who have been referred out to an independent facility where they are still receiving ESRD care as of March 1, 1982. The average age for all patients in our ESRD Network (#28) is only 52.

2) Of the 31 patients presently receiving dialysis at Beth Israel Hospital, 13 are "bounce-backs," patients who have been previously referred to independent facilities for treatment or home training but have been sent back to Beth Israel because of complications requiring care which could not be provided by the independent facility. The 13 complications are as follows:

    a. Clotted artifical arterio-venous fistula requiring repeated femoral vein catheterizations for dialysis.

    b. New cerebral stroke, increasing congestive heart failure and weight loss.

    c. Severe back pain and missing dialysis treatments. (It is common practice for the independent facilities to return patients to hospital based centers when they frequently miss dialysis and thereby contribute to a loss of charges. We should point out our concern as to what will be the fate of such patients with psychological difficulties that often cause them to be difficult treatment problems.)

    d. Severe headaches and psychological reasons.

    e. Increased debilitation, frequent vomiting, diarrhea and medication intolerance.

    f. Bacterial septicemia and ruptured arterio-venous fistula with hemorrhagic shock.

g. Brain trauma with epidural and subdural hematomas causing confusion.

h. Multiple episodes of unconsciousness, seizures and cardiac arrhythmias.

i. Weight loss and intractable severe itching during dialysis.

j. Myocardial infarction and cardiac disease.

k. Systemic lupus erythematosus with pericarditis, pericardial effusion and poorly functioning and clotting AV shunts and fistulae.

l. Malignant hypertension and hyperkalemia.

m. Left leg tibial fracture and fever secondary to cholangitis.

Thus, as of March 1, 1982, 40 percent of our dialysis patients were returnees from independent facilities that were not capable of managing the patients' medical problems. The remaining 60 percent of our population is represented by patients who could not be referred out because of continuing unstable medical conditions and a small number of patients who are awaiting placement to an independent facility. Moreover, these percentages do not represent an aberration. A review of our dialysis patients for the period January 1, 1980 thru February 28, 1982 reveals that of a total of 183 patients, 55 were "bounce-backs" for various medical conditions requiring hospital based care.

3) Most independent facilities are able to function with their patients in chairs during dialysis. In facilities like ours, almost all patients are dialyized in beds. This choice is not merely the result of habit. The use of beds is conditioned by an increased incidence of severe hypotensive shock, seizures, and cardiac arrhythmias which occur in our hospital based patients. Additionally, many of our patients require costly and labor intensive equipment such as cardiac monitoring, not normally found in the independent units and certainly not found in a home based situation.

The rate setting methodology also seems to be inappropriate and unfair in our situation since it assumes that all facilities will seek to maximize the number of treatments provided in the patient's home in order to lower the facilities' average cost per treatment. As previously stated, our facility retains only unstable patients who are unsuitable for an independent facility or in-home dialysis and has no opportunity to take advantage of this technique.

We foresee little ability for providers like the Beth Israel to adapt to the proposed new rates. If the rates are effective June 1, 1982, we project a fiscal 1982 gross violation for Beth Israel of $300,420. The picture becomes even more disastrous when projected for fiscal 1983 when Beth Israel's gross violation would increase to $467,300.

Should the prospective reimbursement rates be implemented as proposed, hospitals like Beth Israel will have no choice but to seriously consider discontinuing the provision of ambulatory dialysis. No cost based health care facility can withstand losses of the magnitude we project for such a small program. The effect of this program's loss on other hospital programs will be intolerable. But what is the alternative -- the independent facilities cannot and will not care for these patients. Not only are the independent facilities not competent to provide the care, they are not in business to lose money for their stockholders. What will happen to these patients? Where will they go for treatment?

Sincerely,

David Dolins

David Dolins
Executive Vice President and Director

Robert Brown

Robert Brown, M.D.
Clinical Chief of Renal Unit

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Mitchell T. Rabkin, MD
President

April 6, 1982

Robert Lighthizer, Esq.
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Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, DC 20510

RE: March 15 Hearing on Proposed Reimbursement Rates for End-Stage Renal Disease

Dear Mr. Lighthizer:

The proposed cuts in Medicare reimbursement for the treatments of dialysis patients are of great concern to the nursing staff at Beth Israel Hospital. We believe that the fiscal implications of these cuts for hospital programs such as Beth Israel Hospital's would jeopardize care by decreasing professional services and reducing the ability of clinicians to provide comprehensive and individualized care to patients.

Our patient population is elderly and complex. They have multiple medical and nursing problems which require the close attention of the medical staff and the services of a professional nursing staff. It was, therefore, a great surprise to read in the Federal Register:

> "We have examined age, sex, race and utilization rate (discharges and days of care) differences between hospital-based and free-standing facilities. The differences were small and did not approach statistical significance. We conclude, therefore, that with respect to these measures of patient need, there is no great difference between hospital-based and independent facilities."

Since the opening of the Beth Israel chronic dialysis unit in 1972, the policy regarding transferring patients to the freestanding facilities has always been to transfer the most stable or less seriously ill patients. The patients receiving treatment within our hospital dialysis unit have always been the most unstable, complex patients requiring the multiple services of a tertiary care hospital.

At any given time our patient population consists of the seriously ill patients, new patients to dialysis, patients returning to our center from the freestanding facility for various problems which cannot be handled by that facility, and a few patients lacking co-insurance and therefore financially unacceptable to the freestanding facility in Boston.

Our experience at Beth Israel supports the belief that there exists a definite distinction between the two patient populations. The average age of our dialysis unit patients is 62 which is considerably older than the average age of the Network's patients (52), with a median age of 69. The multiplicity of medical problems which characterizes our patients make the consideration of home dialysis for them impossible, particularly since they are elderly and most lack the family supports which home dialysis requires.

The current medical information system forms are inadequate for adequately describing patients' needs. One example is that when an acutely unstable patient is transferred to our hospital program from a freestanding facility due to complexity of care needs and dies within a 3 month period, we must classify that patient as a transient. The freestanding facility classifies the same patient as a death. This coding system provides no useful information concerning the needs of patients. Transients is a category that generally describes patients traveling and requiring treatment on an interim basis. In no way are the needs of an unstable dying patient equivalent to a patient on vacation. In addition, when Beth Israel does this patient as transient, it fails to describe the time, energy and complexity of the medical and nursing plan during this patient's course of treatment at Beth Israel. Better information systems must be developed if the intent behind HHS regulations is to avoid hardship to patients and families.

Our patient population requires constant monitoring by the medical staff. The complex nursing care requirements of these patients can only be met by a professional nursing staff. We believe that the proposed cuts in treatment costs would result in a significant number of patients on forced home dialysis without proper supports and/or the closing of facilities which could not meet costs. Both of these outcomes significantly decrease services for ESRD patients.

Sincerely,

Paula Rapazzini

Paula Rapazzini, R.N.
Head Nurse, Hemodialysis Unit

Trish Gibbons

Trish Gibbons, R.N.
Director of Medical Nursing

TG-PR/rac

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March 11, 1982

Robert Lighthizer
Chief Counsel, Committee on Finance
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Washington, D.C. 20510

Dear Mr. Lighthizer:

I am writing in reply to COTH GENERAL MEMBERSHIP MEMORANDUM #82-3 dated March 5, 1982, regarding reimbursement rates for end-stage renal disease. I wish to address these comments to a single area of the proposed regulations which has grave implications for present and future kidney patients. Section II-C, which details the proposed new criteria for claiming an exception to the reimbursement rate, fails to provide for the reimbursement of excess costs associated with those few dialysis facilities in which research is conducted concurrently with patient treatment and which, because of this, incur costs in excess of those of comparable facilities in which patient treatment only is provided. To illustrate the nature of this problem, I want to describe the dialysis research facility here at the University of Washington Hospital in Seattle to point out how the very restrictive exception procedure which is proposed will cause the facility to close.

Our facility was opened in 1964 as the world's first home dialysis training unit with the patient treatment "stations" in separate rooms to facilitate one-on-one training. In the late 1960's, this activity was transferred to the Northwest Kidney Center in Seattle, where it presently continues. At that point,approximately a decade ago, the space was converted into a research dialysis unit specifically designed to carry out "blind" research dialysis. By "blind" is meant that the patient agrees to a specific research protocol but is not aware of the day-to-day details of treatment. This is done in order to obtain scientifically objective results. The conduct of this kind of experimentation is labor-intensive, since higher staffing ratios are necessary to perform treatment when the patient is in one room and the artificial kidney apparatus is in another. Additional costs arise as the result of the small size of the facility. While four stations is an ideal size for our research, we lack the large scale of other facilities which enables price discounts on volume purchases of supplies. Overhead costs of our facility also are higher than in facilities whose mission is solely patient treatment because of our affilication with a teaching and research institution.

Because of its unique role, the facility receives from the Seattle area kidney patients who present medical problems which require more than normal medical care and diagnostic evaluation. For example, during the two-year period from July 1978 to June 1980, 83% of the patients treated at the facility had specific medical problems which necessitated additional care beyond that ordinarily required, and in some instances also required the modification of routine treatment to correct these problems. These factors formed the basis for a reimbursement exception request, which was granted to the facility for the 1979 and 1980 fiscal periods.

We strongly advocate home treatment, having done much of the original work which made home dialysis possible nearly 15 years ago and, as already mentioned, we operated the first training facility for home care. As further evidence of this commitment, a higher percent of patients in our ESRD Network #2 is in the home than in any other network in the United States. The proposed reimbursement system which is designed to create added incentives for expanded home dialysis serves to penalize severely our facility, since we are no longer responsible for a home patient population. Consequently, the cost savings which most other facilities will realize from home care as an offset to the higher costs of outpatient treatment are not available to our facility.

During the past several years we have witnessed a progressive reduction in NIH-sponsored research directed toward improving dialysis treatment. This trend has reached such a dismal point that there is now essentially no NIH funding earmarked for this vital work. The only way that facilities such as ours have been able to continue efforts toward improved care has been through the basic support of the Medicare Program supplemented by occasional grants from the private sector. The absence of either source of support would have tragic consequences, for research in this important area would be forced to stop.

The two major goals of our research program are reduction in cost of dialysis and improvement in patient well-being. Our original development of the technique of automated home hemodialysis and of dialyzer re-use is a pertinent example in the cost-saving area. The rediscovery of the value of dialysis against bicarbonate is an example of our research to improve patient well-being.

If the very few dialysis research units such as ours are to survive, we must have an exception to the proposed ceiling. Therefore, we would like to have the phrase "research in dialysis" added to the list of items for which exceptions will be made to the proposed ceiling in the new regulations.

Such an exception easily could be rigidly enforced by a proper review process and would not provide a loophole for getting around the intent of the new regulations. Indeed, such an exception might well encourage other, similarly qualified academically based dialysis units to begin research in this area, which presently is totally neglected due to intra-NIH politics.

Sincerely yours,

Belding H Scribner

Belding H. Scribner, M.D.
Head, Division of Nephrology (Box RM-11)

BHS:al
cc. Mrs. Charlotte Tsoucolas, Office of Senator Henry Jackson
cc. Dr. Carolyn Davis, Administrator, Health Care Finance Administration
cc. Ms. Diana Jost, Staff Assistant, House Committee on Ways and Means

March 23, 1982

Robert E. Lighthizer
Chief Counsel
Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20510

Re: Review of the proposed prospective reimbursement rates for the End Stage Renal Disease (ESRD) Program, Monday, March 15, 1982

Dear Mr. Lighthizer:

Enclosed please find Cordis Dow Corp.'s position paper in opposition to the proposed elimination of the One Hundred Percent Reimbursement Program for ESRD patients as contained within the proposed perspective reimbursement system for the ESRD Program.

We believe that the Program is successful, provides a necessary incentive to both home dialysis patients and providers and is the most cost effective method of providing home patient dialysis equipment.

Cordis Dow Corp. respectfully submits this position paper for the Committee's consideration and review in this matter.

Sincerely,

Thomas J. Scott
Vice President,
Director of Marketing

TJS/ms
enclosure

Position Paper

Statement

Cordis Dow wishes to submit to the record its opposition to the proposed elimination of the One Hundred Percent Reimbursement Program for ESRD patient (P.L. 95-292, Sec. 1881 (e)).

Summary

- The program has been successful.
- The program is more cost effective than the alternative equipment rental program.
- Elimination of the program imposes a real disincentive to prospective home patients.
- Elimination of the program will impose a real disincentive to both the independent and hospital provider - the largest source of home dialysis patients.
- The disincentives resulting from elimination of the program will most likely reduce the number of new home dialysis patients - contrary to the intent of Congress and the Administration.

Rationale

- Administration statistics reveal that approximately 10% of the current home dialysis patients are being served by this program.
- Dr. Christopher Blagg, Director, Northwest Kidney Center in Seattle, with one of the highest home dialysis patient populations in the country, testified that elimination of the program would present a real disincentive to facilities supporting home dialysis.

- Dr. Jeffrey Weilig, Shady Grove Dialysis Center, Rockville, Maryland, testified that elimination of the program will remove any incentive for independent facilities to put patients home.

- Government Accounting Office testified that a comparison to the alternative rental method proved the program to be more cost effective. A model demonstrating this cost difference is contained in Appendix 1.

- National Association of Patients on Hemodialysis and Transplantation (NAPHT) testified that dialysis patients desire choice and incentive. Elimination of the program would be a disincentive and thus counter productive to the aim of increasing the percentage of home patients.

Conclusion

- Since both the dialysis patients (NAPHT) and the dialysis providers (Drs. Blagg and Weilig) believe the elimination of this program presents a real disincentive to home patient dialysis, it is not realistic to expect an increase in the numbers and percentage of home patients.

- This program which is the most cost effective method of providing home dialysis patient equipment, (GAO), should not be eliminated in favor of a more expensive method.

Recommendation

1. Delete Sec. 405.690, Subpart F, of Proposed Rule of "Medicare Programs; End Stage Renal Disease Program: Prospective Reimbursement for Dialysis Services", issued in the Federal Register, February 12, 1982.

2. Continue the One Hundred Percent Reimbursement program for ESRD patients.

Appendix 1

The One Hundred Percent Reimbursement Program is a more cost effective method of providing home patient hemodialysis equipment since it recognizes the reality of long term equipment rental costs versus outright purchase.

The magnitude of this cost difference can be demonstrated through the development of a comparison model of rental versus One Hundred Percent Reimbursement. Currently, there are approximately 10,000 home dialysis patients. Of this total, approximately 5,000 of these patients are home hemodialysis patients. From this point on, it is necessary that we make a series of assumptions. These assumptions are:

1. The prospective reimbursement system is adopted and successful in doubling the number of net home patients over the next six years. (See table 1).
2. There will be some reasonable rental mix of the currently available hemodialysis equipment. (See table 2).
3. All home hemodialysis equipment is rented from the manufacturer and reimbursed by the Medicare intermediary at 80% of the established reimbursement screen. (See table 3).
4. That both the reimbursement screen and the sale price of the hemodialysis equipment increases at a rate of 5% per year. (See table 4).
5. Home patients are added to the program at an equal rate during each calendar year.
6. Given the home patient usage of the equipment (150 treatments per year) compared to incenter usage (624-936 treatments per year), life expectancy is at least 6 years.
7. Installation, maintenance, and repair costs are the same for either a rental or One Hundred Percent equipment.

Given the above assumptions, the comparison model produces the following results.

RENTAL VERSUS ONE HUNDRED PERCENT REIMBURSEMENT

COMPARISON MODEL

YEAR	NET # OF HEMODIALYSIS PATIENTS	NET PATIENT CHANGE	NET CUM. CHANGE	EST. CUM. RENTAL COST ($000)	EST. CUM. 100% REIMBURSEMENT ($000)	DIFFERENCE ($000)	CUM. DIFFERENCE ($000)
1981	5,000	-0-	-0-	-0-	-0-	-0-	
1982	6,000	1,000	1,000	$ 2,076	$ 8,978	-$ 6,902	-$ 6,902
1983	7,000	1,000	2,000	$ 6,534	$ 9,427	-$ 2,893	-$ 9,795
1984	7,800	800	2,800	$10,973	$ 7,918	$ 3,055	-$ 6,740
1985	8,600	800	3,600	$15,360	$ 8,314	$ 7,046	$ 306
1986	9,400	800	4,400	$20,160	$ 8,730	$11,430	$11,736
1987	10,000	600	5,000	$24,929	$ 6,875	$18,054	$29,790
TOTALS:				$80,032	$50,242	$29,790	

1.27 X VALUE @ 5 YEARS

1.60 X VALUE @ 6 YEARS

TABLE 1

NET HOME HEMODIALYSIS PATIENT CHANGE

YEAR	NET # OF HEMODIALYSIS PATIENTS	NET CHANGE	NET CUMULATIVE CHANGE
1981	5,000	-0-	-0-
1982	6,000	1,000	1,000
1983	7,000	1,000	2,000
1984	7,800	800	2,800
1985	8,600	800	3,600
1986	9,400	800	4,400
1987	10,000	600	5,000

TABLE 2

RENTAL MIX OF HOME HEMODIALYSIS* EQUIPMENT

HEMODIALYSIS EQUIPMENT	RENTAL MIX PERCENTAGE
MACHINE 1	10
MACHINE 2	5
MACHINE 3	25
MACHINE 4	5
MACHINE 5	55

* PROJECTION BASED UPON EXISTING MARKET DISTRIBUTION DATA WITH PROPOSED IMPACT OF NEW EQUIPMENT TECHNOLOGY

TABLE 3

SALE PRICE AND MONTHLY RENTAL REIMBURSEMENT FOR HEMODIALYSIS EQUIPMENT

EQUIPMENT	SALE PRICE W/O SERVICE	MONTHLY RENTAL REIMBURSEMENT SCREEN W/O SERVICE	MONTHLY REIMBURSEMENT @ 80% OF SCREEN W/O SERVICE
MACHINE 1*	$14,950	790	632
MACHINE 2	$11,950	590	472
MACHINE 3	$10,000	465	372
MACHINE 4	$ 8,500	415	332
MACHINE 5	$ 7,200	340	272
AVERAGE*	$ 8,978		346

*MACHINE 1 - NEW EQUIPMENT TECHNOLOGY THAT EXPANDS NUMBER OF POSSIBLE HOME PATIENTS.

TABLE 4

SALE PRICE & MONTHLY REIMBURSEMENT INCREASES AT 5% PER YEAR

YEAR	SALE PRICE W/O SERVICE	MONTHLY RENTAL W/O SERVICE
1982	$ 8,978	346
1983	$ 9,427	363
1984	$ 9,898	381
1985	$10,393	400
1986	$10,913	420
1987	$11,458	442

Henry Ford Hospital

DETROIT, MICHIGAN 48202

March 23, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lighthizer:

As providers of Dialysis services to nearly 300 patients in Southeastern Michigan, we are disturbed by the February 12, 1982 proposed rules regarding reimbursement for ESRD services. We wish to oppose the proposed new regulations for the following reasons:

Contrary to the unsupported assumption of the Health Care Financing Administration (HCFA), we think that the impact of the proposed reimbursement system, paying 46% of hospital facilities and 28% of independent facilities less than their costs, will materially affect access to care and deprive Medicare beneficiaries their entitlements. Consequently, a very large percentage of both hospital based and independent facilities will not be able to cover their costs under the proposed system. Henry Ford Hospital services older, urban, more complicated patients. Our ESRD program will not be able to continue it its present form if the proposed rules are passed. We realize that certain providers are abusing the cost exception system and feel that those are the providers that should be restricted, not all ESRD providers.

The methodology used for the proposed rules was based on data collected from cost reporting information during the years 1977 through 1979. HCFA indirectly concedes that the 1980 average cost for outpatient hospital based treatments was $171.00. In addition, no adjustment for cost inflation was added to the proposed rates because HCFA assumes that "the provisions of dialysis services has been characterized by increased efficiencies." We believe that setting prospective rates on cost information reported 3 to 4 years ago is inappropriate. Moreover, since the proposed methodology is a prospective system, some recognition for future as well as current inflationary effects must be included.

The methodology used by HCFA in establishing the proposed rates was designed to arrive at predetermined rates dictated solely for program savings. This was not the specific intent of Congress, nor is it for the specific good of our patients. The basic premises used to determine the proposed rates seriously cloud their credibility. For instance, an arbitrary adjustment factor of 5% was used to accommodate hospitals' cost due to the possibility of the methodology failing to recognize legitimate costs. In a recent Federal subcommittee meeting, the administration of HCFA admitted the adjustment could have been 5, 10, or 20%, but 5% was chosen in the interest of cost savings. We feel that other statements in the methodology also support the arbitrary basis used to determine the proposed regulations, one such is "...the reimbursement level appears to be at an adequate level." We also question the objectivity of the methodology. In a decision memo to the secretary of HHS, two different methods of rate-setting were described by HCFA. We find it curious that both methods came up with the same rates.

In addition, the methodology used to derive the composite rate clearly is not equitable when it combines independent and hospital facilities. HCFA states, currently 10.5% of the treatments provided by independent facilities are home dialysis services. The comparable number for hospital based facilities is 23.5%, currently Henry Ford Hospital has 20.0% of our patients treated at home. By incorporating home and in-center percentages into a composite rate, the proposed regulations provide independent facilities with greater flexibility in terms of reducing composite costs by increasing the percentage of home dialysis.

HCFA admits that hospital facilities incur additional allocated overhead because the facility is subject to the Medicare hospitals financial guidelines. But the differential of $2.10 per treatment allowed for the additional allocation of hospital overhead is not realistic. Our estimate of the difference between our hospital and an independent facility is approximately $34.00 per treatment.

Not only are the cost bases for setting facility rates outdated and inadequate, but the cost information gathered by HCFA regarding home dialysis is clearly misleading. In deriving the home dialysis cost base HCFA collected data from less than 5% of ESRD programs which have home patients and included in the 5% were ten of the largest most efficient home programs. HCFA has stated that it believes 35-40% of all dialysis patients should be dialyzed at home. At Henry Ford Hospital our home patient population is between 15-20% of our total patient population. We do not believe that home dialysis is an appropriate mode of therapy for 35-40% of our population. Without trained, paid personnel in the patient's home, our patients would have to dialyze in our facility. If the cost of trained personnel were added to the cost of home dialysis, there would be no significant cost difference between home and facility treatments. Also, we take offense in that HCFA believes it can influence the numbers of patients prescribed to a certain modality by adding incentives to home dialysis reimbursement. The physician's medical opinion and the patient's own preferences dictate the modality of therapy. The new proposed reimbursement certainly will not change the patient's perference.

In regards to CAPD, HCFA has no basis to state that this modality should be the "preferred treatment for most patients." Preliminary evidence suggests that CAPD may provide an alternative for patients who are prime home hemodialysis patients so this modality will not significantly increase the percentage of home patients. Again, HCFA is premature in assessing the financial "rewards" of CAPD. Supplies represent the major cost of the CAPD treatment, with supply cost being controlled by a virtual oligopoly, the providers have a minimal price leverage.

HCFA, in addition to reducing facility reimbursement, has also proposed decreased payment be made to physicians. When the Alternative Reimbursement Method (ARM) was developed, it was intended to be reflective of a total range of services performed by a nephrologist during a monthly interval. Included in these services, besides dialysis treatment were non-dialysis, on-call, psycho-social and nutritional care of the ESRD patient. ARM was developed to recognize the level of specialist care, cognitive as well as hands-on, provided to the renal patient. The conversion factor of 20 times 13 visits was considered a relative value factor for a broad range of services, only one which related to contact of the patient while undergoing dialysis treatments. If the value factor was related to contacts as HCFA suggests, then the concept could never be adopted for home dialysis patients, since contact is rarely made with the patient during their home treatment. HCFA is attempting to reduce physician fees through a distortion of the basic concept of ARM. HCFA states that it is "assumed a physician will see the patients during every dialysis session"; if this is the case, then how can HCFA substantiate an incentive increase in payment for home dialysis patients.

Additional effects of the reduction of physician reimbursement will result in a lessening of quality care, an increase in physician non-routine service charges, and the resultant effect will be higher cost to the ESRD program.

HCFA, also, proposes that the new regulations will become effective upon publication of the final regulations without any lead time or transition period. We believe this will exaccerbate the administrative disruptions caused by the re-education of the intermediaries, providers and physicians. It is unrealistic to expect providers to adjust so abruptly to massive reductions in reimbursement without major adverse effects on patient care. We also anticipate that because of the substantial changes proposed, the reimbursement system may temporarily grind to a halt, resulting in severe cash flow problems to providers and physicians.

In the proposed regulation, HCFA mentions that periodic rate review should take place. We strongly suggest that these reviews be required annually. Since the rate-setting methodology will be tied to dynamic factors, annual reviews most assuredly will result in rate changes. Also, since the rate of individual facilities is based on an array of costs experienced by all facilities, this rate will be modified yearly.

In summary, we would like to outline the reasons we oppose passage of the proposed regulations as currently stated:

- Use of median costs by HCFA methodology results in 46% of Hospital and 28% of independents being reimbursed at less than their costs.
- Proposed rules will adversely affect access to care.
- Data base of HCFA is three to five years old.
- Methodology uses an arbitrary adjustment factor of 5% for hospitals.
- Composite rate methodology clearly favors independent facilities.
- Overhead allocation differential is not realistic.
- Cost information gathered on home patients is skewed.
- CAPD costs are really yet to be determined.
- The costs of CAPD are controlled by a virtual oligopoly.
- Reduction of physicians fees distort the basic concepts of ARM.
- No lead time or transition period will be allowed.
- No requirement of annual reviews.

The proposed regulations must be re-evaluated and altered significantly so that the ESRD program conforms with the intent of Congress and the needs of patients are met in an orderly fashion.

Sincerely,

Dennis Sal
Vice President
Director of Operations

/ejw

THE MT. SINAI
MEDICAL CENTER

University Circle
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216/421-3919

Barry M. Spero
President

March 19, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lighthizer:

The purpose of this letter is to express the concern of The Mt. Sinai Medical Center regarding the proposed rule which appeared in the February 12, 1982 Federal Register dealing with prospective reimbursement for dialysis treatments.

The Mt. Sinai Medical Center operates a Kidney Dialysis Center for treating 45 to 55 patients per year with each patient being dialyzed approximately three times per week. The Medical Center profile of the typical hemodialysis patient are often ones awaiting transplant or have just returned to the facility with post-transplant complications or rejections. Many suffer acute secondary ailments and our staffing patterns reflect the exceptional intensity of the care and services we provide when compared with those of the average outpatient dialysis program.

We do not provide training for self-dialysis or for home dialysis primarily because the type of patient we treat would not do well on a dialysis program where the responsibility is left to the patient.

We object to the rate setting methodology used in that it does not designate any differences between operating cost and capital related cost nor does it recognize the distinct difference between types of patients or intensity of care of patients.

The Mt. Sinai Medical Center and the patients we serve will seriously be affected by the new rates. We have explored a variety of alternatives

Affiliated with Case Western Reserve University School of Medicine and The Jewish Community Federation

and organizational structures for our Dialysis Center and found that we cannot continue to treat the same type of patient without experiencing a large financial loss. Obviously, choices beyond this point will have catastrophic consequences to our patients.

I strongly urge you and members of the Senate Subcommittee on Health of the Committee on Finance to give further and more indepth thought to the serious consequences that kidney dialysis patients will suffer, not only at Mt. Sinai, but around the country if the proposed rules are placed in effect.

Sincerely,

Barry M. Spero
President

BMS:rp

c.c. Dr. Richard M. Knapp
Mr. Ronald E. Bartlett

Enclosures - 5 copies for Subcommittee membership

Maimonides medical center

MAIMONIDES HOSPITAL
4802 TENTH AVENUE
BROOKLYN, N.Y. 11219
(212) 270-7679
COMMUNITY MENTAL HEALTH CENTER

March 23, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room #2227
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Lighthizer:

In response to your request for comments on the proposed prospective reimbursement rates for the [redacted] I can provide you with the following information concerning the cost of our in-hospital dialysis unit compared with other facilities:

One of the main factors in our relatively high expenditures are the use of Hollow fiber dialysers. These Hollow fiber dialysers are considerably more expensive than Coil dialysers. However, they do have certain advantages medically and technically over the Coil. These advantages relate to the smaller amount of blood priming and the smoothness of dialysis and the relatively lesser incidence of hypotension. Our dialysis population, to a great extent, consists of patients from the immediate area and many of these patients are elderly and have other illnesses besides their kidney disease. A medical decision has been made to use these Hollow fiber dialysers in situations where we feel it is safer to do so. Many of our patients have had a past history of coronary artery disease, myocardial infarction and/or cerebral vascular accidents. These patients as well as others with various other medical problems not only require the use of the more expensive types of dialysers but also require more nursing time and attention and, therefore, a larger nursing staff. Although these patients may not always require hospitalization, they nonetheless require a great deal more care from nurses, physicians and technicians. In addition to the more frequent monitoring of the patients, it is also required that many stat blood tests be performed on them since changes in their potassium, sodium and magnesium levels, hematocrit and blood pressure can have serious and even lethal consequences in this population group. The concentrations of the various chemicals in the dialysate may also have to be regulated on an individual basis and this requires additional nursing and technician time.

Our hospital is reimbursed for these ambulatory out-patient visits without regard to the fact that our patient population is atypical from the point of view of the amount of supplies and care needed. Since our reimbursement rate has not reflected these additional costs, our financial situation as compared with other units handling stable out-patients is unfavorable.

Further reduction of funding for Hemodialysis places a major financial burden on the hospital, and calls into question the ability to continue this program in light of increasing deficits.

Sincerely,

David G. Kaufman Ph.D.

David G. Kaufman, Ph.D.
Administrator for Professional
Affairs

DGK:AZ:lg

cc: L. W. Schwenn
F. W. Hays
Dr. H. Lipner
B. Yankelevitz

Affiliated with the
Federation of Jewish Philanthropies of New York

AGH

allegheny general hospital

320 east north avenue • pittsburgh, pennsylvania 15212-9986

Office of the President
John H. Westerman

412-359-3000

March 11, 1982

Mr. Robert Lighthizer
Chief Counsel
Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20510

Subject: Senate Finance Subcommittee on Health: Hearing on the Proposed Prospective Reimbursement Rates for the End Stage Renal Disease Program

Dear Mr. Lighthizer:

Allegheny General Hospital has a hospital based Renal Dialysis unit that during fiscal year 1981 performed over 13,000 dialysis treatments to patients with End Stage Renal Disease. The proposed regulations will place the future of our program, as well as many others, in jeopardy of our having to discontinue it. For our fiscal year ending June 30, 1982 we are projecting a loss of approximately $300,000 for the Renal Program, a fact that has forced our Board to ask the question whether it should continue to subsidize this program in even greater amounts as forecast under the Proposed Prospective Rates.

Prior to preparing our comments the following were reviewed and analyzed in detail:

- The statement by Richard P. Kusserow, Inspector General on the Involvement of the Office of the Inspector General in the Medicare End-Stage Renal Disease Program, February 23, 1982.
- The statement of Carolyne K. Davis, Ph.D., Administrator - Health Care Financing Administration before the Subcommittee on Intergovernmental Relations and Human Resources Committee on Government Operations, February 24, 1982.
- Proposed Rule - Federal Register/Volume 47 of Friday, February 12, 1982, regarding Prospective Reimbursement for Dialysis Services.

Based on our review and analysis I would like to offer the following comments:

- The proposed regulations appear to be formed soley with the goal of saving the government money and not necessarily providing equitable reimbursement for the services the beneficiaries receive. This becomes even more apparent as the "allegations" that all hospitals are inefficiently run are included in this type of proposal as a justification for reducing reimbursement, a statement that we take strong objection to.

- We believe the true differential between free-standing and in-hospital dialysis clinics is much higher than the $4.00 per unit quoted in the literature. This belief is also supported by Richard P. Kusserow, Inspector General of H.H.S. in his nonconcurrence memorandum of the proposed rates wherein he feels the differential should be $23.33 or $19.33 more than proposed. Although we agree with the Inspector General that the differential should be much higher, we take strong exception with his proposed hospital composite rate of $129.36.

- It appears that the data base on cost used in the literature contain figures intermixed from various fiscal years: 1977, 1978, 1979 which are not adjusted for inflation.

- The normal treatment for a person with End Stage Renal Disease, having coronary disease, is peritoneal dialysis. The proposed regulations will now reimburse peritoneal dialysis at the same rate as hemodialysis. The peritoneal method of treatment has been recognized by H.H.S. as being much more costly due to the time and supplies involved. Not recognizing this fact in the proposed rates is illogical and will result in increased losses for Allegheny General Hospital.

- The literature states that the Physicians are the controlling factor regarding the location in which the patients are treated. Historically our Physicians have tried to expand the Home Dialysis program, but have met with great resistance from the patients themselves. We have been successful in placing over 90 patients on Home Dialysis but do not see a true ability to expand much beyond this point due to the acuity of care needed and the patients' resistance to this treatment. We feel the incentives for home dialysis should be focused toward the patients not the doctors or facilities. Additionally, Allegheny General Hospital previously investigated the reasonableness of providing the equipment for home dialysis but H.C.F.A. refused to grant any assurances of adequate reimbursement on a continuing basis.

- We believe the type of patient treated at Allegheny General Hospital requires a higher acuity of care than those treated at free-standing facilities. This was recently supported by our local H.S.A. during a planning review for our facility during which it was demonstrated that most of our patients' have secondary diagnoses. In addition H.C.F.A. has agreed with this fact in that they have historically granted Allegheny General Hospital ceiling relief. (e.g. 1976 through 1979 - $280,000 was granted), because of the acuity factor we have been able to demonstrate and in turn a higher requirement staffing complement. It should also be noted that we have requests for Ceiling Relief in process for fiscal 1980 and 1981.

We feel that the proposed regulations, if implemented as is, could force many hospital-based Renal Dialysis units out of business, among which most probably would be Allegheny General Hospital.

If you would like additional information or to discuss these issues further, please call me.

Sincerely,

John H. Westerman

John H. Westerman

GJH:JHW:tac

cc: Honorable H. John Heinz, III
Honorable Arlen Spector

RENAL PHYSICIANS ASSOCIATION
OF
NEW JERSEY
35 Kings Highway E.
Haddonfield, N.J. 08033

March 15, 1982

Mr. Robert E. Lighthizer
Chief Counsel
Committee on Finance
Room 2227
Dirksen Senate Office Building
Washington, D.C. 20510

Re: Senate Subcommittee on Health Hearings: ESRD Program
March 15, 1982

Dear Mr. Lighthizer:

Enclosed please find a written statement prepared by the New Jersey Renal Physicians Association for submission and inclusion into the printed record.

In addition to specific comments on questions raised by the Subcommittee, several specific recommendations are suggested for an effective implementation of the dual composite rate.

Thank you.

Sincerely yours,

John P Capelli, M.D.

John P. Capelli, M.D.
Chairman, New Jersey
Renal Physicians Association

JPC/pf
Enclosure

cc: Ms. Sheila Burke
Mr. Edward Mihalski ✓

RENAL PHYSICIANS ASSOCIATION
OF
NEW JERSEY
35 Kings Highway E.
Haddonfield, N.J. 08033

STATEMENT ON
THE PROPOSED PROSPECTIVE REIMBURSEMENT RATES
FOR THE END-STAGE RENAL DISEASE PROGRAM

TO

SENATE FINANCE SUBCOMMITTEE ON HEALTH

HEARINGS

MARCH 15, 1982

John P. Capelli, M.D.,
Chairman
Renal Physicians Association
of New Jersey
March 15, 1982

RENAL PHYSICIANS ASSOCIATION
OF
NEW JERSEY
35 Kings Highway E.
Haddonfield, N.J. 08033

The New Jersey Renal Physicians Association herein submits its comments regarding the hearings on The Proposed Prospective Reimbursement Rates for the ESRD Program held March 15, 1982, by the Senate Finance Subcommittee on Health.

The New Jersey Renal Physicians Association wishes to address the specific (four) points outlined in the Committee's press release, additional relevant areas regarding the February 12, 1982 proposed rulemaking, and proposes to make certain specific recommendations in this matter for an effective implementation of the composite incentive reimbursement system as legislated by Congress.

The New Jersey Renal Physicians Association affirms its support of a dual composite rate system as statutorily provided under PL-95-37. However, as the HCFA attempted to implement the provisions of this statute, many serious shortcomings and defective aspects were promulgated which failed in meeting the intent of Congress. The seriousness of the defects in the NPRM can lead to serious disruptions in the delivery of care and in the quality of care to ESRD patients, a consequence which can and must be avoided.

There has been a desire by some, including planners within HHS/HCFA, for the creation of a single reimbursement rate applicable to both hospital and independent facilities, based on the cost experience of the more cost efficient independent programs. This concept is misleading and has some serious defects. Although one may argue, and justifiably so, that hospital units of comparable size as independents should be able to operate equally as efficient, the negative impact on home dialysis with the single rate will be pronounced.

The majority of home-training is accomplished by hospital-based units (23.5%). If reimbursement to these hospitals for their maintenance dialysis programs is viewed as marginal, or a cost disincentive, the hospitals may either limit their home dialysis to increase their maintenance patient population, rely on independent programs to deliver maintenance services, or choose to terminate their programs entirely. Thus, the single rate approach will have the positive effect of shifting maintenance dialysis services to perhaps less costly facility settings, but with a resultant serious negative impact on the least costly level of care, home dialysis.

Therefore, the dual composite rate goes beyond merely removing disincentives to home dialysis, it takes the important step, heretofore lacking, which is actually to offer incentives towards delivering this modality of care. However, care must be taken, which in developing this methodology, that harmful effects are not laid upon those patients who are truly in need of maintenance, in-center, dialysis.

THE ADEQUACY OF THE DATA ON WHICH THE ADMINISTRATION BASED THE NEW RATES

The HCFA clearly admitted in their proposed rule that there was a lack of sufficient standards against which efficient and economically run units could be judged. It was also admitted that the data base stretched back to 1977 through 1979. There were no adjustments for inflation in the development of the rates. Further, there were unspecified disallowances of 15% for independent facilities, and 3% for hospital facilities. Not knowing what effect valid challenges to these disallowances would have, the final rate could be affected by as much as $19.

Thus, the HCFA attempted to establish a rate setting system with inadequate and outdated data, allowing nothing for inflationary changes. This cannot be accepted as a proper action upon which a reimbursement system is promulgated having enormous impact on providers and patients.

There must be an accurate and valid audit system developed which can be applied for cost acquisition from all ESRD providers of care. This data cost collection must be done on an annual basis and then used for accurate derivation of reimbursement rates on a periodic basis.

THE ADEQUACY OF THE RATE SETTING METHODOLOGY

A major deficiency in the entire methodology stems from HCFA's attempt to circumvent the congressional intent and the statutory provisions in failing to truly develop a dual composite rate. The data appeared to be so manipulated as to arrive at pre-determined cost savings having close to 50% of hospital-based programs placed in serious financial jeopardy.

In deriving the rates, HCFA took the median costs of all facilities and applied this to their formulae, rather than taking the true costs for hospital programs and for independent programs and applying each to the formula. The data was then further manipulated by using the higher percentage of home dialysis for hospital programs in their formula, and the lower percentage of home dialysis for independent programs in their formula, dragging down even further the overall hospital rates. Even the application of overhead costs was manipulated to bring the hospital reimbursement rate down to virtually the same level of the independent facility rates. The data was so manipulated that the final rates reflected an 18% increase above the median costs for independent facilities, and a 2% reduction below the median costs for hospital programs. If the data were applied equally, and the formula valid, how could one group's rates go up, and the other group's rate go down, when there is a disparity of 25% between the two groups at the onset.

Thus, one must be driven to the conclusion that HCFA intended to promulgate its own concepts of the reimbursement system, and essentially ignore the intent of Congress.

THE ABILITY OF PROVIDERS TO ADAPT TO THE NEW RATES

This is clearly another major deficiency in the proposed regulations. With any significant change in reimbursement methodology and rates, a sufficient amount of phase-in time must be permitted to allow intermediaries and providers to adjust. The HCFA allowed for no phase-in period to implement these changes.

In order for any new system of reimbursement to be effectively implemented, a transition process must take place. Secondly, there must be a realistic exception procedure to ensure an equitable application of reimbursement methodology. This exception process must address three major areas of concern:

1) Facilities With Limited or No Home Dialysis Programs:
   These programs will possibly have costs in excess of the proposed rates. Such programs will need a grace period of perhaps 12-18 months to either develop a home-training program of its own, or to arrange for training of patients with an affiliated program. The latter process could result in improved efficiency in existing home dialysis training programs, while precluding the development of several small, inefficient, and perhaps poor quality ones. Once the patient was trained, the referring facility would resume the ongoing monitoring and support for the home patient, thereby collecting the reimbursement and obtaining the financial incentive.

2) Facilities With Unique Situations That Preclude Home Dialysis:
   A procedure for granting exceptions to the application of the composite rate would be developed to accommodate such facilities as pediatric units, or those facilities which provide the majority

of their care for transplant patients or in-hospital patients, or facilities which have an atypical patient mix such as predominately inner city, low income type patients where the home settings are unsuitable or unsafe for home dialysis.

3) Facilities Who Can Demonstrate Higher Costs For Outpatient Component: Facilities whose costs can be validly demonstrated to be in excess of comparable outpatient dialysis costs would then be granted an exception. However, such facilities rates would not be included into the calculation of the overall average costs. This would be necessary to preclude escalation of the composite rate simply because outpatient facilities were recognized as higher than normal.

THE POTENTIAL EFFECT THE NEW RATES WILL HAVE ON PATIENTS AND FACILITIES

The large number of providers whose costs will exceed the proposed reimbursement rates places an unacceptable number of programs and their patients in jeopardy. There could be a significant number of programs which are forced to curtail services, reducing quality of care, and even resulting in denial of care.

THE POTENTIAL EFFECT THE NEW RATES WILL HAVE ON PHYSICIANS AND PATIENT CARE

The drastic proposed reductions in physician reimbursement will not, in any way, increase incentives to home dialysis, but will rather decrease physician availability to patients, cause an increase in charges for non-routine renal care and non-renal care with added program paperwork. The diminution in preventive aspects of renal physician care for the ESRD patient can result in more hospitalizations, the overall effect being an increase in program costs, and not a decrease as stated.

The New Jersey Renal Physicians Association regards the proposed changes in physician reimbursement and the expressed basis for these changes to be seriously flawed. The HCFA is under the impression that the statutes provide such ample discretion in physician reimbursement that virtually any system, any rate, and any covered scope of services can be applied merely through regulatory language. This opinion is not only invalid, but if carried to the extremes proposed, will result in major adverse affects on the ESRD program.

The HCFA appears to imply that because the physician is the primary "decision-maker" in how ESRD treatment is to be furnished, a greater (financial) incentive belongs to the physician. In effect, HCFA is promulgating a fallacious concept that the physician's decision-making regarding where a patient is treated is dictated primarily by economic motives. While it is true that a physician must place an economic value on his time and services, it is untrue to assume that physicians make medical decisions based on economic considerations wholly apart from the benefit to the patient, and contrary to the AMA Code of Ethics. The decision as to what modality of care to recommend for an ESRD patient is a medical one and multi-faceted. If, in fact, an economic issue were the primary factor, then the system as it is currently proposed will pose a serious ethical dilemma for physicians.

It is our position that the current reimbursement system is hardly excessive when viewed in the proper context of the scope of services provided per patient. Further, it is our position that HCFA has attempted to distort the basic concept of the ARM through a lack of understanding of the system and through its conduct of a few very poorly designed and very limited audits by the Bureau of Quality Control.

The renal physician not only provides hands-on treatment in appropriate instances, but equally as important, provides critical cognitive services which have enormous impact on patient care. The renal physician must serve as the patient's primary physician and coordinates treatment in those illnesses requiring other subspecialty medical, surgical, psychiatric consultations, as well as services in such fields as rehabilitation, nutrition, and social services. The renal physician provides appropriate communication between the patient, the patient's family, and provides counseling in medical, emotional, and financial conditions. The renal physician constantly evaluates the patient's symptoms, laboratory, x-ray, and specialized testing data, and through appropriate analysis determines the needs of the patient. The renal physician provides diagnosis, where prompt action means life-saving treatment. The renal physician plays a major role in the health maintenance of the ESRD patient who is frequently on the edge of serious, and costly, hospitalizations. These are some of the scope of services the ARM reflects.

It is a contradiction in terms of the proposed "neutralization" concept, bringing the physician reimbursement rate down to one level, by assuming that all patients will be seen "every dialysis session". If this proposes to justify the reduction in fees by application of the proposed formula, (i.e., 149 dialyses ÷ 12 months = 12.4, the 12.4 is then multiplied by the brief office visit fee), then how does HCFA explain away the absence of physician contact with the patient while undergoing home dialysis treatments, yet applying the same formula rule and reimbursement rate. Further, how could this concept even begin to apply to the CAPD patient. The only way HCFA, or anyone, can justify payment for the home dialysis patient, whether they be hemodialysis, CAPD, or IPD, is to properly recognize the renal physician's cognitive services, as well as the periodic hands-on services, and the the back-up availability of services provided to these patients, and this is, in fact, what is required. That is why the ARM as it was developed conceptually is still valid and applicable to the current modalities of care. The in-center patient is seen more frequently, has a higher level of care, frequently by virtue of age, and complicating medical illnesses. That is why as we carefully scrutinize HCFA's thinking in this matter, it becomes evident that there is a lack of understanding for the ARM concept.

The proposal set forth by HCFA does not meet the statutory intent, which was to provide incentives to home dialysis. The HCFA merely has attempted to provide financial disincentives to in-center dialysis, further jeopardizing physician availability to patient care. Further, it has established a system which permits for further and further reductions in physician reimbursement as the home dialysis rates increase. This can hardly be viewed as an incentive. The proposed system can have the additional effects of increasing consumption of non-routine services, such as hospitalizations, charges for non-renal care, and added program paperwork, resulting in higher overall program costs, with serious adverse effects on the quality of care.

Finally, HCFA has proposed two elements which the New Jersey Renal Physicians Association regard as without legal authority. The HCFA intends to eliminate the Initial Method of Reimbursement because it is stated that it is "...not well suited for promoting home dialysis." There does not appear to be statutory authority for permitting an elimination of this system of reimbursement.

The other element which the New Jersey Renal Physicians Association finds statutory unsound is the elimination of the Medicare Economic Index (MEI) as it applies to all, but only, renal physicians under the Medicare Program. It is our position that HCFA has continually violated the Medicare statutory provisions by its failure to apply the MEI to renal physicians. Under any system of reimbursement, there must be a method for appropriate increases in reimbursement reflective of inflationary and other factors. The HCFA continually discriminates against renal physicians. The proposed rulemaking not only attempts to preclude any future adjustments in physician reimbursement, but tries to do so by again attempting to legislate by regulation.

The New Jersey Renal Physicians Association feels it is appropriate to bring to

HCFA's attention certain conclusions derived in a study on "Compensation of Physicians in the End-Stage Renal Disease Program", prepared under a grant from the HCFA, (Center For Health Services and Policy Research, Northwestern University; Philip J. Held and Mark V. Pauly, 1980). After analyzing the various methods of renal physician reimbursement, the time elements involved in caring for home dialysis and in-center dialysis patients, this independent study concluded, in part, the following:

- Many refinements and qualifications can be made, but it does not appear as though the revenue per hour for physicians treating patients with ESRD is dramatically different than that experienced by internists in general.
- Second, there appears to be a substantial financial incentive to the physician for treating home dialysis patients.
- If we are to assume that physicians are paid the maximum capitation rate ($260 per month in 1978), then physician charges are only 13.3 percent of total dialysis costs. Physician costs are probably only ten percent of the total costs of the program. Even if HCFA were to make any adjustments to physician payment levels, major cost reductions from this aspect of the program alone are unlikely. [Emphasis added].
- Understanding of the impact of physician reimbursement on the incentive to hospitalize and the types of physician care provided to in-patients is an important part of better reimbursement policy.
- Physician earnings under the capitation program do not appear to be grossly in excess of what might be regarded as fair.

If HCFA feels that there is abuse in this physician reimbursement component of the ESRD program, then responsible physicians stand ready to aid in developing a system to address these abuses. However, we reject any attempt by HCFA, or any other agency of HHS, to swing the brush of accusations resulting in broad sweeping indictments of all renal physicians when in fact very few may be truly abusing the system.

If HCFA truly wishes to remove any physician reimbursement disincentives to home dialysis, the following is recommended:

- Availability for physicians under the Initial Method of Reimbursement to receive compensation for their home patients under the ARM.
- There should be no basic changes in the existing ARM methodology, but rather appropriate increase in the reimbursement to renal physicians should occur by applying the Medicare Economic Index to the Office Visit Amount in the formula on an annual basis.
- An additional incentive for the home dialysis patient reimbursement should be 100% reimbursement to the physician rather than 80%, eliminating any added burden to the home patient for co-insurance costs.

Such proposed incentives are affected not at the expense of services for the in-center dialysis patient, and truly meet the intent of Congress.

PROPOSED REGULATORY PROVISIONS AFFECTING HOME DIALYSIS

A. 100% Equipment Reimbursement

According to the statements contained in the NPRM, "...equipment furnished on or after the effective date of the prospective system would no longer be reimburseable at 100%." Further, the NPRM fails to explain how equipment costs for home dialysis would in fact be treated under the prospective reimbursement system, leaving open to question a significant cost element.

Nevertheless, it is our position that the proposal to eliminate the 100% equipment reimbursement for home dialysis is in conflict with the statutory provisions of PL 95-292. There is no statutory repeal of the provisions under the former law in the 1981 Omnibus Reconcilation Act and HCFA has clearly exceeded its authority in arbitrarily removing these equipment costs from its current reimbursement proposal. Inclusion of equipment costs into the composite rate is not only statutorily indefensible, but it also impacts negatively on whatever benefits and incentives would otherwise accrue under the composite rate.

B. Inconsistent Application of Home Dialysis Percentages and Cost Data Into Cost Formula Methodology

In the development of the final rates, HCFA weighed the per treatment costs by the percentage of patients at home and at in-center dialysis, as required by the statute. For the dialysis patients served by hospitals, the percentage of home dialysis rates for all hospital programs were applied (23.5%) to calculate the hospital composite rate. For the dialysis patients served by the independent programs, the percentage of home dialysis rates for all independent programs were applied (10.5%) to calculate their composite rate. However, in applying the labor and non-labor cost components to the formula methodology, HCFA used a median cost figure for all programs, hospitals and independents, combined.

This is an inconsistent and manipulative application of the data which penalizes those programs providing the highest percentage of home dialysis. While it may be true that some of the in-center costs will be offset by revenues in excess of expenses accrued through the home patient reimbursement, hospital programs with overall higher average costs for the in-center programs still will be placed in jeopardy. By applying the cost data and the home dialysis percentages in the manner described, HCFA produced an 18.5% rise above median costs for the independent facility programs, and a 1.5% decrease below median costs for the hospital programs. With the development of any valid methodology and cost data, consistent application of the data in the methodology must be applied not only to be acceptable, but simply to be fair.

C. Patient Billing

The proposed regulations would not limit a patient's right to bill directly. If HCFA permits patients the right to bill directly for home supplies, then the Medicare Program pays double for the supplies, once directly to the patient (or the patient's supplier), and once to the facility through the composite rate reimbursement which includes the cost of supplies.

Clearly this was not intended by Congress, and again is reflective of serious deficiencies in the development of these regulations.

D. Paid Home Dialysis Aides

In the NPRM, HCFA proposes that the cost of paid home aides should not be included in setting any home dialysis payment rate. This was done, according to HCFA, "...to preserve the savings for home dialysis compared to in-facility dialysis."

In the 1978 PL 95-292, there is a statutory provision that requires paid aides to be used where necessary and which requires the cost of such paid aides to be included under the Home Target Rate Reimbursement System. Since HCFA intends to stop all reimbursement under the Home Target Rate Reimbursement, once the composite rate system is implemented, and they state their intention not to include the costs of aides under this setting, it remains unanswered as to just how will aides be reimbursed and just where will these costs be accounted.

It would appear that HCFA has again violated a pre-existing statute by eliminating a cost for home dialysis services through a regulatory provision and not by any statutory repeal.

RECOMMENDATIONS

Facility Reimbursement:

- There should be a mandatory provision for HCFA to collect updated cost data, utilizing a uniform cost-accounting system for all providers before implementation of any new rates.

- There should be a mandatory provision for HCFA to update their cost data, and as a consequence, their rate setting on an annual basis.

- There should be a mandatory provision for inflationary adjustments to occur from the determination of the base year for rate setting to the actual year of implementation.

- There should be a mandatory provision that the rate-setting methodology be:
  1) set forth in proposed rulemaking initially before arbitrarily applied and without publication of any stated rates;
  2) applied in a manner which truly reflects the costs of independent programs and hospital programs, derived for each one's respective cost data;
  3) reflective of overall (national) home dialysis rates, rather than each group's applied separately.

- There should be continued congressional efforts to enforce the provisions and the intent of the dual composite rate with the following modifications:
  1) the composite rate should set a limit on the amount of averaged revenue accrued above costs in those programs with large existing home dialysis programs by computing total program costs, i.e., in-center and home dialysis, on an annual basis;
  2) the composite rate should set a limit of 30%-35% of weighting to

be given to home dialysis in order to preclude an unacceptable decline in in-center dialysis reimbursement rate.

3) the composite rate should provide for a phase-in period of 3 years to permit providers and intermediaries the opportunity to adjust to any new rate system;

4) In order for independent programs, in particular, with no home training capability to receive the benefits of the incentive reimbursement without having to start-up costly, inefficient, or poor quality home dialysis programs, affiliations should be established with regional home-training programs for patient referral. Once trained for home dialysis, the referring center assumes ongoing responsibility and monitoring of the patient, thereby receiving the reimbursement.

5) The exception process should include provisions for unique situations, such as pediatric units, transplant units, and hospital units who serve a large proportion of in-patients (70% of treatments or greater) with an outpatient mix, and facilities who can validly demonstrate higher costs.

6) Any application of labor wage indices must take into consideration pre-existing cost levels such that excess increases in reimbursement do not occur arbitrarily.

7) The costs accrued for home aides, where necessary, must be included in allowable costs for calculation for home dialysis.

8) The 100% equipment reimbursement provision as defined under PL 95-292 must be permitted to remain in force.

9) The allowances for Bad Debts should follow standard Medicare cost accounting procedures.

10) Return on Equity Capital for proprietary facilities should be provided according to standard Medicare cost accounting.

Physician Reimbursement

- There should be a mandatory provision which prevents HCFA from arbitrarily eliminating annual adjustments in renal physicians reimbursement as these adjustments are applied to all other participating physicians in the Medicare Program.
- The improvements in physician reimbursement disincentives to home dialysis can be accomplished by:
    - Establishing the ARM for physicians with patients on home dialysis currently utilizing the Initial Method Reimbursement.
    - Permitting 100% reimbursement to the physicians for all patients on home dialysis, eliminating the co-insurance burden to the home patient.
    - Continuing the existing ARM methodology, which recognizes both the cognitive and hands-on care of the renal physician for the two different levels of ESRD modalities of care.
    - Appropriate increases in reimbursement to renal physicians by applying the Medicare Economic Index to the Office Visit component in the ARM formula on a basis similar to all other participating physicians in the Medicare Program.

HCFA Organization

- There should be a mandatory provision for the creation of a Special ESRD Branch within HCFA composed of a seasoned and adequate staff of knowledgeable bureaucrats to administer the ESRD Program.

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